

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF VIRGINIA  
Alexandria Division**

LOUISIANA HEALTH SERVICE &  
INDEMNITY COMPANY D/B/A BLUE  
CROSS AND BLUE SHIELD OF  
LOUISIANA, and HMO LOUISIANA, INC.,  
on behalf of themselves and all others  
similarly situated,

Plaintiffs,

v.

JANSSEN BIOTECH, INC., JANSSEN  
ONCOLOGY, INC., JANSSEN RESEARCH  
& DEVELOPMENT, LLC, and BTG  
INTERNATIONAL LIMITED,

Defendants.

CIVIL ACTION NO. \_\_\_\_\_

**CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL**

## TABLE OF CONTENTS

I.	INTRODUCTION .....	1
II.	JURISDICTION AND VENUE .....	4
III.	THE PARTIES.....	5
IV.	OBTAINING AND ENFORCING PATENTS .....	7
A.	Although subject to a procedural presumption of validity, patents are not sacrosanct.....	7
1.	Patent applicants must provide full and complete information to the PTO when seeking approval of a patent application.....	7
2.	The “presumption of validity” for patents is a procedural device to assign burdens of proof; it is not a conclusive determination.....	9
B.	“Obvious” inventions are not patentable. ....	10
C.	“Commercial success” as an argument supporting non-obviousness works only if no “blocking patents” exist, preventing others from commercially testing or selling the product.....	10
D.	Patents can be challenged by multiple means.....	13
1.	Patents can be challenged in court proceedings.....	13
2.	Patents can be challenged through the <i>inter partes</i> review system. ....	14
V.	REGULATORY BACKGROUND .....	15
A.	Potential brand drug manufacturers must demonstrate the safety and effectiveness of their new drug and must list in the Orange Book patents they claim cover it.....	15
B.	Potential manufacturers of a generic equivalent of a brand drug must contend with the listed patents and are incentivized to challenge or design around weak patents.....	16
1.	ANDA applicants may challenge the validity of listed patents and the patent holders may sue for patent infringement in response.....	18
2.	Brand drug manufacturers can use the filing of P.IV certifications to delay potential generic competitors through litigation. ....	20
3.	First ANDA filers are entitled to a valuable 180-day exclusivity. ....	21

VI.	ECONOMIC BACKGROUND .....	23
VII.	FACTS .....	25
A.	1994-2011: Abiraterone acetate is invented, patented, developed, approved, and launched as Zytiga.....	25
B.	2007-2010: The PTO rejects as obvious Janssen’s first two attempts to secure a second patent.....	27
C.	2010-2011: Janssen seeks and obtains FDA approval to sell abiraterone acetate. ....	30
D.	2011-2013: The PTO issues three more rejections of Janssen’s attempt to patent the obvious but extends the life of the ’213 patent by three years. ....	31
1.	February 2012: The PTO rejects Janssen’s second patent attempt for a third time. ....	31
2.	September 2012: The PTO issues its fourth rejection of Janssen’s patent application, over obviousness, unexpected results, and commercial success arguments. ....	33
3.	March 2013: The PTO issues its fifth rejection. ....	35
4.	September 2013: The PTO grants a patent term extension on the ’213 blocking patent, following representations from BTG that the ’213 patent claims the only active ingredient in Zytiga.....	36
E.	September 2014: Janssen’s sixth time is the charm, patenting the obvious based on a commercial success argument.....	36
F.	2015: Generic competitors line up to compete with Zytiga, Janssen and BTG pursue litigations they cannot win to prevent competition, and generic manufacturers challenge the ’438 patent at the PTAB.....	40
1.	April – July 2015: Generic competitors line up to compete with Zytiga and Janssen and BTG sue them. ....	40
2.	December 2015: Generic companies ask the PTAB to assess the validity of the ’438 patent. ....	42
G.	2016: The PTAB accepts Amerigen’s petition (making its first determination that the claims of the ’438 patent were likely too obvious to be patented), more generics file petitions for <i>inter partes</i> review, and the ’213 patent expires.....	44

1.	Early summer 2016: Ten more generics file petitions for <i>inter partes</i> review to invalidate the '438 patent as the PTAB initiates a formal review. ....	44
2.	August 2016: Actavis changes its P.IV certification on the '213 blocking patent to a P.III certification, and any semblance of legitimacy to Janssen's litigation disappears. ....	45
3.	Late 2016: Judge McNulty issues his <i>Markman</i> decision, adopting Janssen's narrow definition of "treatment" and "treating" and the '213 patent expires. ....	46
H.	2017: The PTAB grants additional petitions for <i>inter partes</i> review, Janssen and BTG continue their baseless litigations, and generic companies clear regulatory hurdles. ....	46
I.	Early 2018: The PTAB issues three decisions, each finding the '438 patent invalid as obvious. ....	48
1.	January 17, 2018: The PTAB issues its first decision finding the claims of the '438 patent unpatentable. ....	48
2.	January 17, 2018: The PTAB issues its second decision finding the claims of the '438 patent unpatentable. ....	53
J.	Mid 2018: Following a nine-day trial, Judge McNulty finds clear and convincing evidence that the '438 patent is invalid. ....	54
K.	Late 2018 and early 2019: After losing at the district court, Janssen and BTG continue trying to delay generic competition, the courts rebuff them at every turn, and generic competition for Zytiga finally begins. ....	57
L.	Absent the sham litigations, one or more Zytiga generics could have been available in December 2016, and would have been available no later than November 2017. ....	58
M.	Janssen possesses monopoly power over abiraterone acetate. ....	59
VIII.	CLASS ACTION ALLEGATIONS .....	61
IX.	CLAIMS FOR RELIEF .....	64
X.	COMPLIANCE WITH NOTICE REQUIREMENTS. ....	142
XI.	DEMAND FOR JUDGMENT. ....	149
XII.	JURY DEMAND .....	150

Louisiana Health Service & Indemnity Company, d/b/a Blue Cross and Blue Shield of Louisiana (“BCBSLA”) and HMO Louisiana, Inc. (“HMOLA”) (collectively “Plaintiffs” or “BCBSLA”) bring this action on behalf of themselves, and all others similarly situated (“the purchasers”), against defendants Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development LLC (collectively, “Janssen”) and BTG International Limited (“BTG”). These allegations are based on publicly available materials and knowledge, information, and belief.

## I. INTRODUCTION

1. Patents protect innovation and encourage new discoveries. Sometimes, a party can obtain multiple patents relating to the same product. But each patent must protect a novel invention or discovery. If an invention claimed in a patent application is obvious in light of existing technology, it is generally not patentable.

2. However, an invention that is obvious may still be patentable if the patent applicant can prove that “secondary considerations” overcome the obviousness. One such way to do so is to prove “commercial success” of the newly-claimed invention; if the newly-claimed invention was commercially successful, *and the newly-claimed invention was the reason for that success*, then the newly-claimed invention may be worthy of patent protection.

3. Janssen got a patent on the compound abiraterone acetate in 1997. That patent – U.S. Patent No. 5,604,213 (the ’213 patent) – lasted nearly twenty years and expired in December 2016. During the life of the ’213 patent was in place, only Janssen could sell an abiraterone acetate product; no other company could. On April 28, 2011, Janssen got approval from the FDA for Zytiga, abiraterone acetate tablets, for the treatment of prostate cancer in combination with prednisone. For the next five and a half years, because of the ’213 patent, Janssen had a legitimate monopoly on sales of Zytiga. The company made billions of dollars:

U.S. sales of Zytiga went from \$191 million in 2011 to \$463 million in 2012, its first full year on the market. In 2015, U.S. Zytiga sales exceeded \$1 billion.

4. But the '213 patent would not last forever, and Janssen (and its partner BTG) wanted to extend that monopoly. So beginning in 2007 and continuing through 2014, Janssen sought a second patent: on a method of using abiraterone acetate in combination with prednisone to treat prostate cancer.

5. Here's the rub:

- It was well known at the time that abiraterone can be used to treat prostate cancer.
- It was well known at the time that prednisone can be used for the same.
- It was well known at the time that the way in which abiraterone works makes it necessary to administer it with a glucocorticoid, a kind of steroid.
- It was well known at the time that prednisone was a commonly used glucocorticoid; in fact, prednisone had been successfully used in combination with another drug in the same class as abiraterone to treat prostate cancer.

6. Not surprisingly, the United States Patent & Trademark Office (the PTO) repeatedly rejected this second patent application, correctly finding that it was obvious to combine abiraterone acetate and prednisone together to treat prostate cancer, and the claimed invention was therefore not patentable. On *five* separate occasions, the PTO rejected Janssen's application. (Years later the Patent Trial and Appeal Board (PTAB) and district court, under broad and narrow claim constructions respectively, would both reach the same conclusion.)

7. Realizing the futility of trying to persuade the PTO that its claimed invention was not obvious, Janssen pivoted, moving away from trying to prove non-obviousness and instead pursuing a "commercial success" argument. For lucky try number six, Janssen told the PTO that combining abiraterone acetate and prednisone could not possibly have been obvious because of the tremendous commercial success that Zytiga enjoyed. Were the combination obvious, the

argument goes, practitioners would already have been using abiraterone acetate and prednisone in combination to treat prostate cancer and Zytiga would not have been as successful as it has been.

8. In making this argument, though, Janssen never called the PTO's attention to the at-the-time-unexpired '213 patent. It never pointed out that the '213 patent, covering the only active drug compound in Zytiga, prevented anyone other than Janssen from making or selling *any* drug product containing that compound. (This is what is commonly referred to as a "blocking patent."). Zytiga enjoyed commercial success not because it demonstrated the supposed non-obviousness of the combination of abiraterone and acetate but because no one else could make or sell an abiraterone acetate product. As both the PTAB and the district court would later conclude, the existence of the blocking patent defeated any "commercial success" argument.

9. But with no other party present to call the blocking patent to the PTO's attention in 2013, Janssen's ruse worked. The PTO examiner found that "the unexpected commercial success" of Zytiga was sufficient to overcome the finding of obviousness. And on that basis – and that basis alone – United States Patent No. 8,822,438 (the '438 patent) issued.

10. To protect Janssen's monopoly, Janssen and BTG then asserted the '438 patent in infringement litigation that they both knew they could never ultimately win in the courts. Their goal was not to win a litigation victory, though; it was simply to delay generic competition. In that sense, Janssen and BTG did win. Their wrongful conduct delayed generic competition by more than one year – and during that time, Zytiga was among the most profitable drugs sold by Janssen's parent company, Johnson & Johnson. United States sales of Zytiga for the twelve

months ending December 31, 2017 were \$1.228 billion. In 2018, United States sales of Zytiga climbed to \$1.771 billion.

11. Absent the defendants' unlawful conduct, generic competition for Zytiga would have entered as early as December 2016 and no later than October 2017. Instead, the defendants' unlawful conduct prevented generic manufacturers from entering the market with competing abiraterone acetate products for more than year, delayed the entry of additional generic competitors, and has cost purchasers hundreds of millions of dollars in overcharge damages. Plaintiff and the proposed class seek to recover damages, including treble damages, under the state antitrust and consumer protection laws enumerated below or in the alternative, damages under § 2 of the Sherman Act<sup>1</sup> and §§ 4 and 16 of the Clayton Act<sup>2</sup>.

## **II. JURISDICTION AND VENUE**

12. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action involving common questions of law or fact in which the aggregate amount in controversy exceeds \$5,000,000, exclusive of interest and costs, there are more than one hundred members of the class, and at least one member of the putative Class is a citizen of a state different from that of one of the defendants.

13. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1332(d), and 1337(a).

14. The Court also has jurisdiction over this action pursuant to § 2 of the Sherman Act and §§ 4 and 16 of the Clayton Act.

---

<sup>1</sup> 15 U.S.C. § 2.

<sup>2</sup> 15 U.S.C. §§ 15(a), 26.

15. The defendants transact business within this District and/or have agents in and/or can be found in this District.

16. Venue is appropriate within this District under 28 U.S.C. § 1391. A substantial part of the events or omissions giving rise to the claims asserted herein occurred before, and involved, the PTAB which is located in Alexandria, Virginia.

17. Venue is also appropriate within this District under § 12 of the Clayton Act<sup>3</sup>.

18. The Court has personal jurisdiction over each of the defendants. The defendants have transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme throughout the United States, including in this District. The scheme has been directed at, and has had the intended effect of causing injury to individuals and companies residing in or doing business throughout the United States, including in this District.

### **III. THE PARTIES**

19. Plaintiff Louisiana Health Service & Indemnity Company, d/b/a Blue Cross and Blue Shield of Louisiana is not for profit health insurance company organized and existing under the laws of the state of Louisiana. BCBSLA provides and manages health benefits to more than 1 million participants, members, and beneficiaries primarily in the state of Louisiana, as well as throughout the U.S. BCBSLA also provides third-party administrative services for members of self-funded employee health plans. BCBSLA has paid all or part of the cost of its participants' purchases of Zytiga, and its AB-rated generic equivalents during the relevant time period.

20. Plaintiff HMO Louisiana, Inc. is a domestic health maintenance organization licensed to conduct business in the state of Louisiana. HMOLA is a wholly owned subsidiary of BCBSLA. HMOLA provides and manages health benefits to participants, members, and

---

<sup>3</sup> 15 U.S.C. § 22.

beneficiaries primarily in the state of Louisiana, as well as throughout the U.S. HMOLA has paid all or part of the cost of its participants' purchases of Zytiga, and its AB-rated generic equivalents during the relevant time period.

21. Defendant Janssen Biotech is a corporation organized and existing under the laws of Pennsylvania, with its principal place of business at 800/850 Ridgeview Drive, Horsham, PA 19044.

22. Defendant Janssen Oncology Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 10990 Wilshire Blvd., Los Angeles, CA 90024.

23. Defendant Janssen R&D is a limited liability company organized and existing under the laws of New Jersey, with its principal place of business at 920 Route 202 South, Raritan, NJ 08869.

24. The three entities identified in the preceding three paragraphs are referred to individually and collectively herein as "Janssen."

25. Defendant BTG is a company organized and existing under the laws of the United Kingdom, with its principal place of business at 5 Fleet Place, London, EC4M 7RD United Kingdom.

26. The defendants' wrongful actions described in this complaint are part of and were taken in furtherance of the illegal monopolization scheme and restraint of trade alleged herein. These actions were authorized, ordered, and/or undertaken by the defendants' various officers, agents, employees, or other representatives while actively engaged in the management of the defendants' affairs within the course and scope of their duties and employment and with their actual, apparent, or ostensible authority.

#### IV. OBTAINING AND ENFORCING PATENTS

**A. Although subject to a procedural presumption of validity, patents are not sacrosanct.**

27. Section 101 of the Patent Act provides that “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” To be patentable, subject matter must be, *inter alia*, novel, non-obvious, and particularly described.

28. The protections afforded by patents must strike a delicate balance between creating incentives that lead to creation, invention, and discovery and impeding the flow of information that might spur invention.

**1. Patent applicants must provide full and complete information to the PTO when seeking approval of a patent application.**

29. The process by which a patent applicant seeks a patent consists of a series of communications between the applicant and the PTO examiner to whom the application is assigned. Other potentially interested parties, such as scientists who have published closely related work, drug companies who may be pursuing similar drugs, or potential competitors who may be planning to practice a similar invention, are generally not allowed to participate in this dialogue.

30. It is the responsibility of the applicant (and/or the attorney or agent who is prosecuting the application) to accurately explain the invention to the examiner, point out any misunderstandings of or errors made by the examiner, place before the examiner all relevant material and information known to the applicant, and fully and accurately explain the relevance of that material and information to the examiner. That is why applicable regulations impose upon

applicants (and their representatives) a duty of candor and good faith in their dealings with the PTO.

31. The PTO processes thousands of patent applications each year. The PTO is overworked, under-funded, and faces massive backlogs. Examiners, on average, spend less than 20 hours reviewing and assessing each application. Most examiners are not lawyers, despite having to assess and respond to legal arguments put before them by the patent applicant's counsel. In reality, the examiner almost always knows less about the invention and technical field than the patent applicant.

32. These conditions are ripe for abuse, particularly where, as in the pharmaceutical industry, patents are a gateway to potentially billions of dollars in sales.

33. Precisely because patents are generally obtained in an *ex parte* setting, with an informational imbalance and no participation by anyone but the applicant and examiner, compliance with the duty of candor and good faith is essential in preventing improper conduct before the PTO, and in avoiding the issuance of patents that will not withstand full scrutiny.

34. The duty of candor and good faith is designed to provide the PTO with the information necessary for effective and efficient decision-making. Examiners and other PTO personnel place great reliance on applicants and inventors to fulfill their duty of candor and good faith. Examiners are trained to believe that applicants and their attorneys are complying with that duty. Generally speaking, the PTO accepts representations from inventors and their attorneys at face value and expects that the duty of candor and good faith is being followed: that there are no half-truths, misleading statements, misrepresentations, or material omissions from inventors and attorneys.

35. The Manual of Patent Examining Procedure reminds attorneys that submission of misleading or inaccurate statements may render the resulting patents unenforceable: “The submission by an applicant of misleading or inaccurate statements of facts during the prosecution of applications for patents has resulted in the patents issuing on such applications being held unenforceable.”

**2. The “presumption of validity” for patents is a procedural device to assign burdens of proof; it is not a conclusive determination.**

36. Once issued, patents are generally presumed to be valid. This presumption emanates from a deference given to the expertise of the PTO.

37. Although subject to a procedural presumption of validity, patents are not bulletproof. The presumption of validity associated with an issued patent is not a conclusive determination that the patent is, in fact, valid; it is simply a procedural device that allows reviewing bodies to assign the appropriate burdens in proceedings challenging the validity of an issued patent.

38. Patents are routinely invalidated or held unenforceable, either upon re-examination by the PTO, through a review by the PTAB, by court decision, or by jury verdict. A patent can be invalidated for a variety of reasons, including lack of novelty, obviousness, indefiniteness, enablement, or fraud or inequitable conduct.

39. When assessing this procedural presumption of validity, understanding the information actually presented to the PTO at the time it was making its decision is important. While not directly altering the ultimate burden of proof on a party challenging this presumption, evidence not considered by the PTO may carry more weight than evidence that was considered, and go further towards meeting the challenger’s burden. If the PTO did not have all material

facts before it when making its initial patentability decision, its considered judgment may lose significant force, and the burden to overcome the presumption may be easier to sustain.

**B. “Obvious” inventions are not patentable.**

40. One reason why a claimed invention may be denied a patent, or why an issued patent may later be invalidated, is a determination that the invention was, in fact, “obvious.”

41. A patent claim is invalid as obvious if the purported differences between the subject matter sought to be patented and the prior art are such that the subject matter would have been obvious to a person of ordinary skill in the art (a POSA). In other words, if the prior art and the general knowledge of a POSA would be sufficient to teach all the parts of the claim, the patent claim is obvious and generally cannot be allowed.

42. The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, (3) the level of ordinary skill in that art, and (4) so-called secondary evidence of non-obviousness.

43. A patent applicant can attempt to overcome an obviousness rejection by pointing to “secondary considerations,” also referred to as objective indicia of obviousness, such as the commercial success of the claimed invention, a long-felt but unsolved need for the claimed invention, and the failure of others in attempting to make the claimed invention.

**C. “Commercial success” as an argument supporting non-obviousness works only if no “blocking patents” exist, preventing others from commercially testing or selling the product.**

44. The law presumes that if an idea were obvious, normal market forces would already have caused a product embodying that idea or claimed invention to be made available (or use of the method of that idea/claimed invention to already be occurring). So if a patent applicant can prove (1) the commercial success of its product embodying the idea or claimed invention and

(2) a causal relation, or “nexus,” between a product embodying that invention and that success, it may be that the idea or claimed invention was not as obvious as thought; in such instances, the commercial success of the product may be probative on the obviousness inquiry.

45. When others are legally barred from commercially testing the ideas of the newly-claimed invention, though, the commercial or financial success of the product is irrelevant to the obviousness analysis. If the commercial success of the product is due to the fact that no one else can practice the idea or claimed invention, then commercial success arguably says nothing about obviousness.

46. Existing patents can serve to legally bar others from commercially testing an idea or claimed invention. Indeed, that is the point of patents.

47. If an already-existing patent relates to the general subject matter of a newly-claimed invention and could support a claim of infringement to the newly-claimed invention, it must be considered when assessing commercial success.

48. Such patents – ones that might be infringed by practice of a later invention – are commonly referred to as “blocking patents.” The existence of a blocking patent may deter others from investing the resources needed to make, develop, or market such a later “blocked” invention because of the risk of infringement liability and associated monetary and injunctive remedies. The clearer the “block,” the greater the deterrence.

49. Of course, not all prior patents act as blocking patents. For example, a patent covering only a particular formulation of a drug would not prevent another company from selling that drug using a different formulation. Likewise, a patent covering only a particular type of delivery mechanism would not prevent another company from selling the product using a

different delivery mechanism. And a patent covering only a particular method of using a drug would not prevent another company from selling that drug for a different use.

50. But where the prior patent covers the underlying product itself, such as a drug compound, it blocks *all* other potential uses. Without the ability to sell the drug compound itself, there is no motivation to try and develop a new formulation of the drug or a new delivery mechanism or method of use for that drug. The drug compound patent would prevent the marketing of any such product; it “blocks” all others from even trying to bring a product to the market.

51. The deterrent effect of a blocking patent has no impact on the owner or licensee of the initial patent. So, if the owner or licensee of a drug compound patent wants to seek another, related patent, it can do so without fear of being sued for infringement on the initial patent. Where a later invention is patented by the owner or licensee of an earlier blocking patent, understanding the deterrent effect is relevant to assessing why others may not have pursued the “blocked” invention, and hence, to evaluating any claimed secondary considerations.

52. Courts have made clear that, if all other variables are constant, a blocking patent diminishes possible rewards from a non-owner’s or non-licensees’ investment activity aimed at an invention whose commercial exploitation would be infringing, thus reducing incentives for innovations in the blocked space by non-owners and non-licensees of the blocking patent.

53. A blocking patent, therefore, can be evidence that discounts the significance of the claim that nobody but the blocking patent’s owners or licensees arrived at, developed, and marketed the invention covered by the later patent.

54. Where such a blocking patent exists, commercial success is of “minimal probative value” and is not, by itself, sufficient to justify a finding of non-obviousness. The evaluation of

commercial success as a means of overcoming obviousness is a fact-specific inquiry, which should include assessment of the effect of any blocking patents on possible competition.

**D. Patents can be challenged by multiple means.**

55. To address the fact that “bad” patents can sometimes slip through and gain approval, patents have long been challengeable in court. More recently, Congress supplemented the litigation route with various administrative remedies, including an *inter partes* review system.

**1. Patents can be challenged in court proceedings.**

56. In the case of pharmaceutical patents, a generic can prevail in patent infringement litigation by showing that its product does not infringe the patent (and/or that the patent holder cannot meet its burden to prove infringement). It may also, or in the alternative, show that the patent itself is invalid or unenforceable. For example, a patent is invalid or unenforceable when the disclosed invention is obvious in light of prior art. A patent is also invalid or unenforceable when an inventor, an inventor’s attorney, or another person involved with the application, with intent to mislead or deceive the PTO, fails to disclose to the PTO material information known to that person to be material, or submits materially false information to the PTO during prosecution.

57. In those circumstances, the PTO’s decision to issue a patent does not substitute for a fact-specific assessment of (i) whether the applicant made intentional misrepresentations or omissions on which the PTO relied in issuing the patent, and (ii) whether a reasonable manufacturer in the patent holder’s position would have a realistic likelihood of succeeding on the merits of a patent infringement suit.

58. As a statistical matter, if the parties litigate to a decision on the merits, it is more likely that a challenged patent will be found invalid or not infringed than upheld. The Federal Trade Commission (“FTC”) reports that generics prevailed in 73% of Hatch-Waxman patent

litigation cases resolved on the merits between 1992 and 2002. An empirical study of all substantive decisions rendered in every patent case filed in 2008 and 2009 similarly reports that when a generic challenger stays the course until a decision on the merits, the generic wins 74% of the time.

**2. Patents can be challenged through the *inter partes* review system.**

59. In 2011, Congress passed the Leahy-Smith America Invents Act (“AIA”) to address a widely held concern that invalid patents were being issued and enforced, to the detriment of both innovation and the economy.

60. A centerpiece of the AIA is the system of *inter partes* review. Through this system at the PTO, members of the public can challenge issued patents. The grounds for an *inter partes* review is limited to patentability issues under § 102 (novelty) or § 103 (obviousness); even then, the challenge can only be based on prior art consisting of patents or prior publications.

61. The advent of *inter partes* review created a less expensive and more efficient venue for patent validity challenges than challenges in district court. *Inter partes* review proceedings are overseen by technically educated judges, skilled in the sciences of a particular proceeding.

62. An *inter partes* review commences when a party – often an alleged patent infringer – petitions the PTAB to reconsider the PTO’s issuance of an existing patent and invalidate it on the ground that it was obvious or anticipated by prior art.

63. The PTAB will grant a request for an *inter partes* review only if the challenger of the patent shows “a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”<sup>4</sup> The PTAB must decide the review within one year of

---

<sup>4</sup> 35 U.S.C. § 314(a).

the institution date.

64. Once commenced, the review proceeds before the PTAB in much the same way as standard litigation. The parties conduct discovery, file briefs, and engage in oral argument.

65. The PTAB proceedings have become an effective method of challenging improperly granted patents: *only 4%* of all Board petitions end with a final written decision in which all claims are upheld as patentable; 69% of all PTAB petitions that have reached final written decisions have led to findings that *all* of the patents' claims were unpatentable.

## V. REGULATORY BACKGROUND

### A. Potential brand drug manufacturers must demonstrate the safety and effectiveness of their new drug and must list in the Orange Book patents they claim cover it.

66. Under the Food, Drug, and Cosmetics Act (the FDCA), drug companies that wish to sell a new drug product must file a New Drug Application (an NDA) with the FDA. An NDA submission must include specific data concerning the safety and effectiveness of the drug, including information from at least two clinical trials.

67. Approval of an NDA by the FDA does not typically grant any exclusive marketing rights but a few such FDA-granted exclusivities do exist. One is the New Chemical Entity ("NCE") exclusivity, which applies to products containing chemical entities never previously approved by FDA either alone or in combination. NCE exclusivity generally lasts 5 years, although it can be extended to 7.5 years in certain circumstances. FDA-granted exclusivities are different from (but can run concurrently with) any marketing exclusivity procured by patent protection.<sup>5</sup>

---

<sup>5</sup> And regulatory exclusivities are not necessarily bars to generic entry. For example, some can be overcome by carving out information in the label or for other reasons. *See, e.g.*, 21 C.F.R. §§ 314.94(a)(8)(iv), 314.127(a)(7); 21 U.S.C. § 355a(o).

68. An NDA applicant must also submit to the FDA information about each patent that purportedly covers the drug product, including methods-of-using the drug product, described in the NDA and for which “a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.”<sup>6</sup> The FDA then publishes this information in a digest titled *Approved Drug Products with Therapeutic Equivalence Ratings*, known as the Orange Book.

69. The FDA performs only a ministerial act in listing patents in the Orange Book. The FDA does not have the resources or authority to verify the manufacturer’s representations for accuracy or trustworthiness. Thus, the FDA relies completely on the manufacturer’s truthfulness about the Orange Book information it supplies, including whether the listed patent is valid and may reasonably be asserted against a generic applicant.

70. Once a brand manufacturer lists a patent in the Orange Book, that listing puts potential generic competitors on notice that the brand considers the patent to cover its drug. The listing triggers important regulatory consequences.

**B. Potential manufacturers of a generic equivalent of a brand drug must contend with the listed patents and are incentivized to challenge or design around weak patents.**

71. The Hatch-Waxman Amendments, enacted in 1984, simplified regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs.<sup>7</sup> A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application (“ANDA”). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer’s original NDA and must

---

<sup>6</sup> 21 U.S.C. § 355(b)(1), (c)(2).

<sup>7</sup> See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355).

show that the generic contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug and that it is bioequivalent, *i.e.*, absorbed at the same rate and to the same extent as the brand. The FDA assigns generics that meet these criteria relative to their brand counterparts an “AB” rating.

72. The FDCA and Hatch-Waxman Amendments operate on the principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic would be present in the blood of a patient to the same extent and for the same amount of time as the brand counterpart.<sup>8</sup>

73. Through the Hatch-Waxman Amendments, Congress sought to expedite the entry of less expensive generic competitors to brand drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers’ incentives to create new and innovative products.

74. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches and ushering in an era of historically high profit margins for brand pharmaceutical manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenues for brands and generics totaled \$21.6 billion; by 2013, total prescription drug revenues had climbed to more than \$329.2 billion, with generics

---

<sup>8</sup> 21 U.S.C. § 355(j)(8)(B).

accounting for 86% of prescriptions. Generics are dispensed about 95% of the time when a generic form is available.

**1. ANDA applicants may challenge the validity of listed patents and the patent holders may sue for patent infringement in response.**

75. An ANDA must include one of the following four certifications with respect to each patent listed by the NDA holder as covering the branded drug it seeks to produce:

- i. Paragraph I: no such patent has been listed in the Orange Book;
- ii. Paragraph II: any such listed patent has expired;
- iii. Paragraph III: the date on which such patent will expire and the intent not to market or sell the product until that date; or
- iv. Paragraph IV: such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.<sup>9</sup>

76. An ANDA applicant may agree to wait for FDA approval until after a listed patent expires, in which case it submits a Paragraph III or “P.III” certification. As the ANDA filer is not seeking to market a generic product prior to patent expiry, no litigation claiming infringement results.

77. An ANDA applicant may also decide to challenge the listed patent or patents in the hopes of getting to market before patent expiry. In this case, the ANDA filer submits a Paragraph IV or “P.IV” certification.

78. Upon receipt of a P.IV certification, the patent holder may assess whether it is entitled to commence litigation. The ANDA filer’s stated intent to market its product prior to patent expiry is considered a technical act of constructive infringement. So, the patent holder

---

<sup>9</sup> *Id.* § 355(j)(2)(A)(vii)(I)-(IV); *see also* 21 C.F.R. § 314.94(a)(12)(i)(A). The FDCA provides only one circumstance in which an applicant with a pending ANDA need not certify to a listed patent, but that exception, relating to method-of-use patents, is not applicable here. 21 U.S.C. § 355(j)(2)(A)(viii).

would have standing to bring such a suit if it had a legitimate basis to allege infringement. However, nothing in the Hatch-Waxman Act compels the institution of an infringement suit. Instead, the conditions of Rule 11 still apply, and the patent holder is required to analyze the contents of the ANDA applicant's notice and certification, as well as the legitimacy of its patent(s), before electing to file suit.

79. Often, when such litigation is filed, the generic company will focus its arguments on basic claims of patent invalidity or non-infringement, rather than claiming outright fraud by the patentee in obtaining the patent. This is a practical consideration; invalidity or non-infringement may be easier and less time-consuming to prove in court. And it has the same effect; the patent will be judicially determined *not* to prevent the generic from marketing its product.

80. Many times, an ANDA applicant will submit a P.III certification as to some Orange Book-listed patents and a P.IV certification as to others. When that happens, only the patents as to which a P.IV certification was submitted can be asserted in litigation against that ANDA filer.

81. The ANDA applicant submits the certifications to the FDA. Once the FDA alerts the ANDA applicant that it has received the ANDA and is beginning substantive review of it, the ANDA applicant must notify the patent holder of any P.IV certification. This notice must include a description of the legal and factual basis for the ANDA applicant's assertion that the patent is invalid or not infringed.<sup>10</sup> The statute prohibits an applicant from providing such notice prior to FDA's formal receipt of the application for substantive review.<sup>11</sup>

---

<sup>10</sup> 21 U.S.C. § 355(j)(2)(B)(iv)(II).

<sup>11</sup> 21 U.S.C. § 355(j)(2)(B)(ii).

**2. Brand drug manufacturers can use the filing of P.IV certifications to delay potential generic competitors through litigation.**

82. If a generic manufacturer files an ANDA containing a P.IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement.

83. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the paragraph IV certification, the FDA generally will not grant final approval on that ANDA until the earlier of (i) the passage of 30 months, or (ii) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA.<sup>12</sup> This period is commonly referred to as the "30-month stay."

84. Any 30-month stay afforded by the Hatch-Waxman Amendments is specific to the ANDA(s) which contained the requisite PIV certifications.

85. Where the ANDA relates to a drug with an NCE exclusivity, the 30-month stay may last even longer. For NCEs, the FDA may not accept an ANDA for a drug containing the same active moiety for a period of five years from the date of the NDA's approval, with one

---

<sup>12</sup> 21 U.S.C. § 355(j)(5)(B)(iii). The brand/patent holder can choose to sue the generic after 45 days, including waiting until the generic has launched its product, but doing so would not trigger the automatic 30-month stay of FDA approval and the brand must instead satisfy the showing required to obtain a preliminary injunction to prevent the generic launch.

By enabling a brand manufacturer to bring suit in response to a paragraph IV certification, the Hatch-Waxman Amendments create a procedural mechanism through which the brand and generic manufacturer can resolve their patent dispute *before* the generic's intended launch date. Thus, such a system prevents the delay to generic entry that such a suit would otherwise cause.

If a patent is listed in the Orange Book after an ANDA is submitted but before it is approved, the applicant for the pending ANDA generally must amend its application and provide an appropriate certification for the newly listed patent and the attendant notice. Nonetheless, a patent listed after the date an ANDA was accepted for filing (*i.e.*, the date the FDA determines it was substantially complete) will not trigger a 30-month stay for that application. 21 U.S.C. § 355(j)(5)(B)(iii).

exception: if the ANDA contains a P.IV certification of patent invalidity or non-infringement, an ANDA may be submitted *four* years after the NDA approval, one year earlier.<sup>13</sup> In that situation, when legitimate patent infringement litigation is timely filed, any appropriate 30-month stay is “extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval” of the NDA.<sup>14</sup> In effect, this can increase the 30-month stay by up to another year.

86. Until the court issues a decision finding the patent invalid or not infringed or until 30 months (or longer if an NCE) has passed, the FDA may grant “tentative approval” to the ANDA filer, recognizing that the ANDA is approvable, but cannot grant final approval, which would allow the generic manufacturer to market its product.

87. If the challenging generic company obtains a favorable district court decision, and has tentative approval, it meets FDA requirements for manufacture and sale and from a regulatory perspective is clear to launch, even if the patent at issue has not yet expired. In that case, the generic manufacturer may choose to launch before the patent expires (though may be subject to damages if it is found to infringe a valid patent).

### **3. First ANDA filers are entitled to a valuable 180-day exclusivity.**

88. Potential ANDA competitors may be classified as first filers or subsequent filers.

89. To encourage manufacturers to seek approval of generic versions of brand drugs, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003<sup>15</sup> provides an incentive to challenge weak patents. The incentive is given to the first applicant – the first filer – to submit a substantially complete ANDA containing a P.IV certification and thus the first

---

<sup>13</sup> 21 U.S.C. § 355(j)(5)(F)(ii); 21 C.F.R. § 314.108(b)(2).

<sup>14</sup> 21 U.S.C. § 355(j)(5)(F)(ii).

<sup>15</sup> Pub. L. No. 108-173, 117 Stat. 2066 (Dec. 8, 2003).

applicant to undertake the risk of facing patent infringement litigation. The reward is an opportunity to be the only ANDA generic on the market with the brand for a 180-day period: the FDA cannot approve subsequent ANDAs for the same product that contain P.IV certification until after this six-month exclusivity has run.<sup>16</sup>

90. If multiple ANDAs are filed on the same day containing P.IV certifications, and no earlier such ANDAs were filed, those ANDA applicants share the 180-day exclusivity if successful in challenging the patent(s).

91. The 180-day window is referred to as the first-filer's six-month or 180-day "exclusivity" but that is a bit of a misnomer. An NDA holder (such as Janssen) can launch a so-called "authorized generic" version of its own brand under its own NDA at any time: these "authorized generics" are often the same pills in different bottles and sold at a lower price point. Brand manufacturers frequently license a third party to sell its authorized generic beginning at the same time as ANDA generic entry as a means to recoup some of the sales they would otherwise lose.

92. During the 180-day exclusivity period, the first filer is the only ANDA-approved generic manufacturer on the market. In the absence of competition from other generics (ANDA or authorized), during the 180-day exclusivity period, a first-filer generic manufacturer generally makes about 80% of all of the profits that it will ever make on the product.

93. The Supreme Court has recognized that "this 180-day period of exclusivity can prove valuable, possibly 'worth several hundred million dollars'" to the first filer.

94. Where patent protection is viewed as weak, ANDAs with P.IV certifications are

---

<sup>16</sup> The first filer can, in some circumstances, forfeit this exclusivity; the requirements for obtaining and retaining this 180-day exclusivity period are described at 21 U.S.C. § 355(j)(5)(B)(iv), (5)(D).

often filed on the first possible day; in the case of drugs with an NCE exclusivity, that is exactly four years after the NDA was approved.

## **VI. ECONOMIC BACKGROUND**

95. The marketplace for the sale of prescription pharmaceutical products in the United States is unusual. In most industries, the person who pays for a product is also the person who chooses the product. When the same person has both the payment obligation and the choice of products, the price of the product plays a predominant role in the choice of products. Consequently, manufacturers have a strong incentive to lower the price of their products to maintain profitability.

96. The pharmaceutical marketplace, in contrast, is characterized by a “disconnect” between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing certain drugs to patients unless they can present a prescription written by their physician. This prohibition introduces an anomaly into the pharmaceutical marketplace between the payment obligation and the product selection. The patient (and in many cases his or her insurer) has the obligation to pay for the pharmaceutical product, but his or her doctor chooses which product the patient will buy.

97. In 1984, Congress sought to ameliorate the “disconnect,” by authorizing the manufacture and sale of generic pharmaceuticals under the Hatch-Waxman Amendments. Since the passage of the Hatch-Waxman Amendments, every state has adopted drug product selection laws that either require or permit pharmacies to substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician specifically directs that substitution is not permitted). In this way, price reenters the product selection decision at the pharmacy counter, lessening the pharmaceutical marketplace “disconnect.” When a therapeutically equivalent generic is introduced and not prevented from competing, brand manufacturers can no longer

exploit the “disconnect,” their monopoly power dissipates, and some of the normal competitive pressures are restored.

98. Because generic versions of branded drugs contain the same active ingredients, and are determined by the FDA to be just as safe and effective as their branded counterparts, the only material differences between generic drugs and their branded counterparts are their prices and manufacturers. Because generic versions of branded products are commodities that cannot be differentiated, the primary basis for generic competition is price.

99. Typically, generics are at least 25% less expensive than their branded counterparts when there is a single generic competitor. They are 50% to 80% (or more) less expensive when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a bioequivalent generic drug usually results in significant cost savings to all drug purchasers.

100. Once a generic hits the market, it quickly captures sales of the corresponding brand drug, often 80% or more of the market, within the first six months after entry. In one study, the FTC found that on average, within a year of generic entry, generics had captured 90% of corresponding brand sales and (with multiple generics on the market) prices had dropped 85%. As a result, competition from generics is viewed by brand manufacturers, such as Janssen, as a grave threat to their bottom lines.

101. Until the generic version of a brand drug enters the market, there is no bioequivalent generic to substitute for, and thus compete with, the branded drug, so the branded drug manufacturer can continue to profitably charge supra-competitive prices. As a result, brand drug manufacturers, well aware of the rapid erosion of branded drug sales by generic drugs, have a strong incentive to delay the start of generic drug competition into the market. Brand manufacturers often seek to extend their monopolies, sometimes resorting to illegal ones,

including fraud on the PTO and subsequent sham litigation against generics seeking to enter the market.

102. The Hatch-Waxman Amendments have significantly advanced the rate of generic drug launches while also ushering in an era of historically high profits for brand drug manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling branded drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, annual prescription drug revenue for branded and generic drugs totaled \$21.6 billion; by 2013, total annual prescription drug revenue had soared to \$329.2 billion.

## VII. FACTS

### A. **1994-2011: Abiraterone acetate is invented, patented, developed, approved, and launched as Zytiga.**

103. Prostate cancer results from the uncontrolled growth of abnormal cells in the prostate gland. Once a prostate cancer tumor develops, androgens such as testosterone promote prostate cancer growth. At its early stages, localized prostate cancer is often curable with local therapy including, for example, surgical removal of the prostate gland and radiotherapy. However, when local therapy fails – as it does in up to a third of men – the disease progresses into metastatic cancer (*i.e.*, it spreads from the prostate into other parts of the body).

104. The enzyme 17 $\alpha$ -hydroxylase/C<sub>17,20</sub>-lyase (“CYP17”) is involved in testosterone synthesis, and CYP17 inhibitors have for decades been known to be useful in the treatment of cancer, specifically androgen-dependent disorders like prostate cancer.

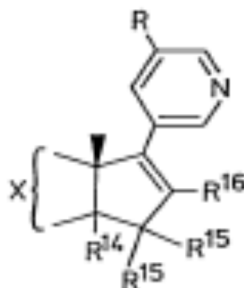
105. Abiraterone acetate, a prodrug of abiraterone,<sup>17</sup> is a CYP17 inhibitor, and considered a second-line therapy for the treatment of prostate cancer.

---

<sup>17</sup> A prodrug is a biologically inactive compound that the body can metabolize to produce a drug.

106. Abiraterone was first discovered in the early 1990s by a group of scientists at the Institute of Cancer Research (ICR). Those scientists were familiar with research from the 1980s involving ketoconazole, another CYP17 inhibitor, and set about making a drug molecule that could mimic some of the properties of ketobonazole.

107. On September 30, 1994, those scientists, including Susan E. Barrie, Michael Jarman, Gerard A. Potter, and Ian R. Hardcastle, filed Patent Application No. 08/315,882, covering the class of compounds to which abiraterone acetate belongs. As the patent's specification described, the "invention relates to 7-substituted steroids and their use in the treatment of androgen-dependent and oestrogen-dependent disorders, especially prostatic cancer and breast cancer respectively." The claimed invention related to drug compounds having the following general formula:



108. After a series of rejections, the inventors convinced the PTO that one particular feature of the claimed compounds (a mandatory double bond at the 16, 17 position and position 14 can only be substituted with halogen or C<sub>1-4</sub>alkyl) was sufficiently non-obvious so as to warrant patentability.

109. On February 18, 1997, the PTO issued this application as U.S. Patent No. 5,604,213 (the '213 patent or the '213 blocking patent), assigned to British Technology Group Limited.

110. In 2004, Cougar Biotechnology obtained an exclusive license to the '213 patent from British Technology Group. Janssen acquired Cougar Biotechnology in May 2009.

**B. 2007-2010: The PTO rejects as obvious Janssen's first two attempts to secure a second patent.**

111. On August 24, 2007, Cougar, through two of its scientists, filed patent application number 11/844,440 (the '440 application), listing 36 claims.

112. On December 29, 2009, following Janssen's acquisition of Cougar, PTO examiner San-ming Hui noted that claims 1-26 were drawn to a method of treating cancer, while claims 27-36 were direct to a composition for the treatment of cancer. When an application claims two or more distinct inventions, the Patent Act, 35 U.S.C. § 121, permits the PTO to require the applicant to restrict the application to one of the inventions. Examiner Hui required Janssen to choose between its method claims and composition claims.

113. In response, Janssen cancelled claims 1-36 and submitted new claims 37-63 relating to a "method for the treatment of a prostate cancer in a human comprising administering to said human a therapeutically effective amount of abiraterone acetate or a pharmaceutically acceptable salt thereof and a therapeutically effective amount of prednisone" (claim 37), a "method for the treatment of a refractory prostate cancer in a human comprising administering to said human a therapeutically effective amount of abiraterone acetate or a pharmaceutically acceptable salt thereof and a therapeutically effective amount of prednisone" (claim 48), and various dependent claims deriving from claims 37 & 48.

114. On April 8, 2010, examiner Hui issued her first rejection of claims 37-63 as being unpatentable over two pieces of prior art. Specifically, examiner Hu found that a 2004 article by

A. O'Donnell on the results of clinical trials of abiraterone (2004)<sup>18</sup> teaches (a) abiraterone acetate is a known CYP17 inhibitor which can be used to suppress testosterone level in prostate cancer patients, (b) 800 mg of abiraterone acetate is useful in suppressing the serum testosterone level, and (c) concomitant glucocorticoid therapy may be needed for continuous use of abiraterone acetate. She also found that a 1996 article by IF Tannock *et al.*<sup>19</sup> “teaches 10 mg of prednisone in combination with other anti-cancer drugs as effective in treating refractory hormonal-resistant prostate cancer.” Thus, it would have been obvious to one skilled in the art to employ both abiraterone acetate and prednisone to treat prostate cancer including refractory prostate cancer, and the motivation to do so would have been present since abiraterone acetate provided a new mechanism of action in treating prostate cancer.

115. On July 8, 2010, Janssen submitted what would be its most substantive response to examiner Hui: 10 pages of counter-argument to the April 8 rejection, claiming:

- a. Neither O'Donnell (2004) nor Tannock (1996) discloses using abiraterone acetate and prednisone together for the treatment of prostate cancer;
- b. Neither O'Donnell (2004) nor Tannock (1996) provide any reason to modify their teachings to arrive at a method of treating prostate cancer with a combination of abiraterone acetate and prednisone;
- c. The patients in the O'Donnell (2004) study were not allowed to take concomitant steroids (and, thus O'Donnell (2004) actually teaches away from the co-administration of steroids);
- d. O'Donnell (2004) concludes that abiraterone acetate is potentially useful in causing reductions in testosterone levels and is thus potentially useful as a second-line treatment of patients who have become refractory to gonadotrophin-releasing hormone agonists;

---

<sup>18</sup> A. O'Donnell, et al., “Hormonal Impact of the 17 $\alpha$ -hydroxylase/C<sub>17,20</sub>-lyase Inhibitor Abiraterone Acetate (CB7630) in Patients with Prostate Cancer” (O'Donnell 2004).

<sup>19</sup> IF Tannock, et al., “Chemotherapy with mitoxantrone plus prednisone or prednisone alone for symptomatic hormone-resistant prostate cancer” J. Clin. Oncol., 1996; 14:1756-1764 (Tannock 1996).

- e. There are no disclosures of prednisone in O'Donnell (2004) and no suggestion to modify its administration of abiraterone acetate to also administer prednisone;
- f. O'Donnell (2004) concludes that it is unknown whether or not it might be useful to administer a glucocorticoid with abiraterone acetate, and that further study is needed, thus, at most O'Donnell (2004) provides an invitation to experiment;
- g. Tannock (1996) discloses the results of a study concerning whether chemotherapy using mitoxantrone, along with prednisone, provides a better palliative response than prednisone (and showed no significant difference in survival rates);
- h. Tannock (1996) chose mitoxantrone for specific reasons and there is no suggestion of using another drug, including abiraterone acetate, especially since abiraterone acetate and mitoxantrone are two different types of drugs; and
- i. Neither O'Donnell (2004) nor Tannock (1996) identified a "problem" in using abiraterone acetate without prednisone or vice-versa.

116. Janssen also made an "unexpected results" argument, pointing to a newly published article by Danila *et al.*<sup>20</sup> on a clinical study of patients with progressive metastatic castration-resistant prostate cancer who were administered abiraterone acetate together with prednisone. Janssen argued that the results of Danila 2010 unexpectedly showed: (a) abiraterone acetate and prednisone resulted in antitumor effects; (b) a decline in the levels of prostate-specific-antigen, demonstrating antitumor activity; (c) a potential for reversing clinical resistance to abiraterone acetate; and (d) a lowered incidence of mineralocorticoid-related toxicities.

117. On September 24, 2010, examiner Hui again rejected claims 37-63.

118. She rejected Janssen's lack of motivation to combine argument, noting that the initial rejection "resides in the fact that both the herein agents are known to be useful in treating prostate cancer. Since abiraterone acetate provide[s] a new mechanism of action in treating prostate cancer and prednisone is known to be useful in treating refractory prostate cancer,

---

<sup>20</sup> Danila *et al.* "Phase II Multicenter Study of Abiraterone Acetate Plus Prednisone Therapy in Patients with Docetaxel-Treated Castration-Resistant Prostate Cancer," *J. Clin. Oncol.* Vol. 28, no. 9, pp. 1496-1501 (March 20, 2010) (Danila 2010).

concomitant employment of both compounds into a single method useful for the very same purpose, treating prostate cancer, would be considered *prima facie* obvious.”

119. She rejected Janssen’s teaching away argument, noting that O’Donnell (2004) was trying to determine the effects of abiraterone acetate, and thus it would have been improper to administer another drug that has an endocrine effect, such as steroids, to the patients.

120. And she rejected Janssen’s unexpected results arguments, noting that the claimed unexpected results were not “commensurate with the scope of the subject matter recited in the claims.”

121. Janssen made no further attempts to support the claims in the ’440 application, and the PTO issued a notice of abandonment as to the ’440 application.

**C. 2010-2011: Janssen seeks and obtains FDA approval to sell abiraterone acetate.**

122. On December 18, 2010, Janssen filed an NDA seeking FDA approval to sell tablets containing abiraterone acetate, bearing the tradename Zytiga.<sup>21</sup>

123. On April 28, 2011, the FDA approved Janssen’s NDA for the sale of Zytiga.

124. The recommended dose of Zytiga is 1000 mg (either two 500 mg film-coated tablets, or four 250 mg uncoated tablets) to be taken orally once daily, along with 5 mg of prednisone to be taken twice daily. The active ingredient in Zytiga tablets consists of non-micronized abiraterone acetate.

125. Following approval of the NDA, Janssen submitted the ’213 patent for listing in the FDA’s Orange Book as covering Zytiga.

---

<sup>21</sup> The NDA was initially filed by Ortho Biotech Oncology Research and Development, a unit of Cougar Biotechnology, Inc.

126. In 2011, United States sales of Zytiga were \$191 million; they would soon reach over \$1 billion a year.<sup>22</sup>

**D. 2011-2013: The PTO issues three more rejections of Janssen's attempt to patent the obvious but extends the life of the '213 patent by three years.**

**1. February 2012: The PTO rejects Janssen's second patent attempt for a third time.**

127. While awaiting FDA approval of Zytiga, Janssen was also renewing attempts to obtain a second patent. On February 24, 2011, Janssen scientists filed Patent Application No. 13/034,340 (the '340 application), identifying it as a continuation of the '440 application, and re-asserting the same 36 claims originally set out in the '440 application.<sup>23</sup>

128. As she had with the earlier '440 application, examiner Hui determined that the '340 application actually claimed two distinct inventions and required Janssen to choose between its method claims and composition claims. And as it had in the now-abandoned '440 application, Janssen would elect to prosecute the method claims rather than the composition claims.

129. On December 21, 2011, Janssen cancelled all 36 claims in the '340 application and proposed 20 new method claims, numbered 37-56. The new claims were directed to "[a] method for the treatment of a prostate cancer in a human comprising administering to said human a therapeutically effective amount of abiraterone acetate or a pharmaceutically acceptable salt thereof and a therapeutically effective amount of prednisone."

---

<sup>22</sup> In 2012, its first full year on the market, Zytiga's United States sales had reached \$463 million; they climbed to \$750 million in 2013. Zytiga sales continued to rise: By 2014 they were \$971 million, and in 2015 they exceeded \$1 billion.

<sup>23</sup> This application was a continuation of U.S. Patent Application No. 11/844,440, filed on August 24, 2007, and claimed the priority date of provisional U.S. Patent Application No. 60/921,506, filed on August 25, 2006. Both were filed by Cougar, on assignment from its scientists Auerbach and Belldgrun; Cougar, at that point, was owned by Johnson & Johnson. From here on out, the complaint will refer to the patent application as Janssen's.

130. On February 3, 2012, examiner Hui rejected the patent in its entirety, finding the newly-proposed claims obvious in light of O'Donnell (2004) and Tannock (1996).

131. As before, examiner Hui explained that O'Donnell (2004) "teaches abiraterone acetate is known to be an inhibitor of 17 $\alpha$ -hydroxylase/C17,20-lyase, which can be used to suppress testosterone level in prostate cancer patients" and "teaches 800 mg of abiraterone acetate as useful in suppressing the serum testosterone level." And as before, examiner Hui further noted that O'Donnell (2004) "also teaches that concomitant glucocorticoid therapy may be needed for continuous use of abiraterone acetate."

132. While examiner Hui recognized that O'Donnell (2004) did "not expressly teach the use of [the steroid] prednisone in the method of treating prostate cancer" and did not "expressly teach the use of the herein claimed dosage and regimen for prednisone and abiraterone acetate," she again noted that Tannock (1996) did just that: "Tannock et al. teaches 10 mg of prednisone in combination with other an[ti]-cancer drug as effective in treating refractory hormonal-resistance prostate cancer."

133. Combining these two prior art references, examiner Hui concluded that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to employ both prednisone and abiraterone acetate, in the dosage herein claimed, together in a method of treating prostate cancer, including refractory prostate cancer."

Since abiraterone acetate provide a new mechanism of action in treating prostate cancer and prednisone is known to be useful in treating refractory prostate cancer, concomitant employment of both compounds into a single method useful for the very same purpose, treating prostate cancer, would be considered prima facie obvious (See *In re Kerkhoven* 205 USPQ 1069 (CCPA 1980)). Treating refractory prostate cancer with abiraterone acetate would be reasonably expected to be effective since abiraterone provides a new mechanism of action against prostate cancer. O'Donnell et al. provides an additional motivation to

concomitantly employ prednisone since employing replacement glucocorticoid such as prednisone would ensure the safety and effectiveness of abiraterone acetate.

134. Examiner Hui further explained that the “the optimization of result effect parameters (e.g., dosage range, dosing regimens) is obvious as being within the skill of the artisan. The optimization of known effective amounts of known active agents to be administered is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.”<sup>24</sup>

**2. September 2012: The PTO issues its fourth rejection of Janssen’s patent application, over obviousness, unexpected results, and commercial success arguments.**

135. Approximately five months after receiving the PTO’s third rejection, Janssen responded on July 3, 2012, acknowledging the two prior art references, but arguing that O’Donnell (2004) and Tannock (1996) only “suggest that the combination of abiraterone acetate and prednisone would be obvious to try.” According to Janssen, “[n]othing in the art teaches or suggests that abiraterone acetate in combination with prednisone would be a particularly useful combination for cancer treatment.” In so arguing, Janssen urged an incorrect interpretation of the obviousness case law.

136. Janssen went further, also asserting that two secondary considerations of non-obviousness enabled it to traverse the examiner’s prima facie obviousness rejection: unexpected results and commercial success.

---

<sup>24</sup> In addition to her obviousness rejection, the examiner provisionally rejected claims 37-56 of the ’340 Application for non-statutory double patenting based on Janssen’s co-pending Patent Application No. 12/898,149 (the ’149 application). In plain English, the ’340 was duplicative of another Janssen patent application. Because the PTO had not yet issued a patent based on the ’149 application at the time of the examiner’s rejection, the examiner clarified that her double patenting rejection was only provisional: it would only take effect if the PTO issued a patent based on the ’149 application. Janssen informed examiner Hui on July 3, 2012 that it had abandoned the ’149 application.

137. First, Janssen contended that “the claimed invention produces unexpected results.” To support this argument, Janssen referenced a 2011 study published in *Nature Reviews Clinical Oncology* that found that Janssen’s claimed invention successfully lowered the pain associated with abiraterone treatment and reduced a certain type of tumor cell. Janssen urged that “the claimed invention produces the unexpected results of increased survival, reduced pain, and lower levels of a biomarker connected with survival.”

138. Second, Janssen claimed that its “invention has experienced an impressive commercial success.” Contending that Zytiga is a commercial embodiment of the claimed invention approved for sale in the U.S. in April 2011, Janssen emphasized that “[w]ithin the first year of release, worldwide sales were over \$400 million.” Thus, according to Janssen, “not only did the claimed invention enjoy immediate commercial success, this commercial success grew over the first year of commercial availability.”

139. On September 11, 2012, in a final office action, examiner Hui issued a final office action, rejecting both of Janssen’s arguments on secondary consideration.

140. She found Janssen’s unexpected results to be “unpersuasive”: “Because abiraterone and prednisone are known to be individually effective in treating prostate cancer,” their “additive effective is expected.”

141. Janssen’s commercial success contentions fared no better. Examiner Hui noted that “gross sales figures do not show commercial success absent evidence as to market share, or as to the time period during which the product was sold, or as to what sales would normally be expected in the market.” And “[i]n the instant case, . . . no evidence of commercial success was provided.”

**3. March 2013: The PTO issues its fifth rejection.**

142. Janssen tried again, requesting on January 11, 2013 that the examiner reconsider her final action and citing a new reference—an article published in the *New England Journal of Medicine*—in support of its unexpected results argument. Janssen made no new arguments regarding Zytiga’s commercial success.

143. But again, examiner Hui found Janssen’s argument unpersuasive. On March 4, 2013, she issued another final rejection, expressly rejecting all of Janssen’s arguments as they pertained to claimed “unexpected results.” Examiner Hui again noted that as “abiraterone and prednisone are known to be individually effective in treating prostate cancer,” an “at least additive effective is expected.”

144. By this point, the writing was indelibly etched into the wall. Scientists were well aware, long before the ’438 patent’s 2006 priority date that androgen hormones such as testosterone promote prostate cancer growth and therapies aimed at suppressing androgen production were a mainstay of prostate cancer treatment. “First line” treatments such as surgical or chemical castration could eliminate most androgen production, but residual androgen produced by adrenal glands could eventually support cancer growth. By the 1990s, researchers knew that CYP17 inhibitors, such as abiraterone and ketoconazole, effectively suppressed both testicular and adrenal androgen production. And abiraterone was recognized as being especially selective and potent. Scientists also recognized that since CYP17 inhibitors suppressed synthesis of beneficial adrenal hormones, concomitant administration of a replacement glucocorticoid was likely necessary. And synthetic glucocorticoids such as prednisone had been used for palliative effects in treating refractory prostate cancer since the 1950s, and a 1998 study showed other anti-prostate cancer activity associated with prednisone. Janssen could dispute none of this.

**4. September 2013: The PTO grants a patent term extension on the '213 blocking patent, following representations from BTG that the '213 patent claims the only active ingredient in Zytiga.**

145. In the meantime, Janssen's partner worked to prolong the protection of the '213 patent. The '213 patent was set to expire on February 18, 2014. On June 22, 2011, BTG filed an application for a patent term extension on the '213 patent. A patent term extension is intended to compensate a patent applicant for delays occurring during the prosecution of the patent before the PTO. Such an application must be filed within 60 days of the regulatory approval of the product, and at least one claim of the patent must cover the product or a method of using the product.

146. In its application for a patent term extension, BTG noted that the FDA "has approved New Drug Application ("NDA") No. 202379 for ZYTIGA (abiraterone acetate). The active ingredient of ZYTIGA is abiraterone acetate." BTG also represented that the '213 patent "claims the active ingredient of the approved product which is abiraterone acetate."

147. On September 25, 2013, examiner Bottino (the examiner who handled the original application for the '213 patent) granted a patent term extension for the '213 patent. The PTO determined, based on the representations made by BTG, that since the claims of the '213 patent "cover the human drug product ZYTIGA (abiraterone acetate)," an extension of 1,029 days was warranted. The expiration of the '213 blocking patent was set at December 13, 2016, granting BTG, and its licensee Janssen, an additional 1,029 days – nearly three years – of patent life.

**E. September 2014: Janssen's sixth time is the charm, patenting the obvious based on a commercial success argument.**

148. Rather than accept the examiner's repeated rejections, Janssen revived its failed commercial success argument. On June 4, 2013, Janssen submitted a new response, re-asserting Zytiga's commercial success as grounds for patentability.

149. This time, Janssen provided the FDA-approved label for Zytiga, along with a December 2012 FDA News Release noting that the agency had decided to expand Zytiga's use for late-stage prostate cancer. Additionally, Janssen submitted two news releases from the FDA (dated June 17, 2010 and August 31, 2012) and a Janssen slideshow, dated May 2013.

150. Janssen claimed that these references showed that Zytiga was a market leader with both chemo-refractory prostate cancer patients (patients who have previously received chemotherapy treatment) and chemo-naïve prostate cancer patients (patients who have not previously received chemotherapy treatment). Janssen emphasized Zytiga's success over two other cancer treatments: Jevtana, which the FDA approved a year before Zytiga, and Xtandi, which the FDA approved a year-and-a-half after Zytiga.

151. At no time during the patent prosecution did Janssen inform examiner Hui that the '213 blocking patent *prevented any other company from even trying to bring an abiraterone acetate product to the market*. Janssen never called examiner Hui's attention to the fact that such a "blocking patent" existed. Janssen intentionally and deliberately refrained from mentioning the '213 blocking patent when pressing its commercial success argument because it knew that the existence of such a blocking patent would render its purported evidence of commercial success to be of minimal, if any, probative value.

152. Based on Janssen's new arguments and the limited evidence Janssen put before her, examiner Hui reversed course and issued a notice of allowance to Janssen on July 3, 2013. In support of this allowance, the examiner provided a single justification: "The unexpected commercial success of the launch of the drug obviates the rejection under 35 U.S.C. § 103(a)."

153. As issued, claim 1 of the '438 patent recites:

A method for the treatment of a prostate cancer in a human comprising administering to said human a therapeutically effective

amount of abiraterone acetate or a pharmaceutically acceptable salt thereof and a therapeutically effective amount of prednisone.

154. After receiving the notice of allowance, Janssen began papering the file with dozens of additional references. On October 3, 2013, Janssen disclosed 25 prior art references, all of which were “Other Prior Art – Non Patent Literature Documents.” On October 25, 2013, the examiner maintained her allowance for “the same reasons of allowance as previous[ly] communicated in the previous notice of allowance.”

155. On January 10, 2014, Janssen disclosed twelve more references in a second information disclosure statement, again putting them all in the “Other Prior Art – Non Patent Literature Documents” category. On February 11, 2014, the examiner accepted them without comment and maintained her allowance because “[t]he commercial success of the combination of prednisone and abiraterone to treat prostate cancer obviate the rejection under 35 USC 103(a).”

156. On May 9, 2014, Janssen submitted a third information disclosure statement containing 29 more references. As before, most (twenty-six) of these references were non-patent literature documents, although this submission also contained three patent-related documents. One was an abandoned United States patent application (20060030608) for anti-aromatase compounds and two were foreign patent references (EP2478907, the European counterpart to the ’340 application and WO2006027266, relating to site and time controlled release mechanisms). These three references would be the only ones cited in the ’438 patent.

157. In addition to these references, Janssen disclosed “the existence of commonly owned pending U.S. Patent Application Serial Nos. 11/844,440.” Janssen notified the examiner that the ’440 application had been “published and is therefore publicly available in PAIR. Moreover, the Patent Office has issued one or more Office Actions in this application.” Janssen

“invited” the examiner “to review the prosecution of this application to determine its impact, if any, on the prosecution of the present application.” However, although Janssen had already submitted over 50 new references, post-allowance, to the PTO, Janssen did not submit a copy of the ’440 application, claiming that it did not want to “overwhelm the Examiner with an overly large IDS.” Janssen also did not mention that the ’440 application had been declared abandoned more than three years earlier, on April 14, 2011.

158. On May 30, 2014, Janssen submitted a fourth information disclosure statement containing eight new references. Again, Janssen made no mention of the ’213 blocking patent.

159. On June 2, 2014, the examiner again affirmed her allowance. And again, the sole reason given was “[t]he commercial success of the combination of prednisone and abiraterone to treat prostate cancer obviate the rejection under 35 USC 103(a).”

160. On June 16, 2014, Janssen made its final submission, along with eight more non-patent references. Still absent from the references supplied to the PTO was the ’213 blocking patent. On August 13, 2014, the PTO issued notice of a projected patent number and issue date.

161. On September 2, 2014, the ’340 application issued as U.S. Patent No. 8,822,438 (the ’438 patent), claiming “methods for treating cancer” comprising “administ[r]ation of] a 17c-hydroxylase/Czo-lyase inhibitor, such as abiraterone acetate, in combination with at least one additional therapeutic agents such as an anti-cancer agent or a steroid.” The twenty approved claims all specify use of abiraterone acetate and prednisone.

162. The ’213 blocking patent was not cited to the PTO during the prosecution of the ’438 patent, and it does not appear in the References Cited portion of the ’438 patent.

163. Subsequent to the issuance of the ’438 patent, there was a proceeding to correct inventorship in which Dr. Johann S. de Bono was added as an inventor to the ’438 patent. BTG

is the owner of Dr. de Bono's inventions and thus asserts co-ownership of the '438 patent along with Janssen.

**F. 2015: Generic competitors line up to compete with Zytiga, Janssen and BTG pursue litigations they cannot win to prevent competition, and generic manufacturers challenge the '438 patent at the PTAB.**

**1. April – July 2015: Generic competitors line up to compete with Zytiga and Janssen and BTG sue them.**

164. On April 28, 2015, the first day on which ANDAs could be filed, multiple generic companies submitted ANDAs seeking FDA approval to launch generic Zytiga. Based on publicly-available FDA approval letters, at least five generic companies filed on this date; other estimates indicate that at least ten generics did so.

165. These generic ANDA filers promptly provided notice to Janssen of their ANDA filings and the certifications contained therein:

<b>Generic company</b>	<b>Notice letter date</b>	<b>P.IV on '213 patent?</b>	<b>P.IV on '438 patent?</b>
Actavis	June 22, 2015	Yes <sup>25</sup>	Yes
Amneal	July 10, 2015	No	Yes
Apotex	July 7, 2015	No	Yes
Citron	June 25, 2015	No	Yes
Dr. Reddy's	July 9, 2015	No	Yes
Mylan	July 9, 2015	No	Yes
Par	June 26, 2015	No	Yes
Sun	June 25, 2015	No	Yes
Teva	July 7, 2015	No	Yes
Hikma/West Ward	June 24, 2015	No	Yes
Wockhardt	June 24, 2015	No	Yes

---

<sup>25</sup> Actavis, the only ANDA filer who submitted a P.IV certification on the '213 blocking patent, subsequently changed that to a P.III certification and stipulated with Janssen that it would not seek to sell generic Zytiga prior to the patent's expiration on December 13, 2016.

166. On July 31, 2015, Janssen and BTG filed a single lawsuit against eleven generic companies in the District of New Jersey. The case was assigned to Judge Kevin McNulty. The filing of this lawsuit triggered the Hatch-Waxman 30-month stay as to the approval of each of their Zytiga ANDAs, a stay that would be extended a year to October 27, 2018 because of Zytiga's NCE exclusivity.<sup>26</sup>

167. Of the eleven different generic companies named by Janssen in a single lawsuit, only one of them, Actavis, had submitted a P.IV certification as to the '213 blocking patent. That is, ten of the eleven defendants made clear that they did not intend to sell generic abiraterone acetate until at least December 13, 2016, when the '213 blocking patent expired. As to those ten generic defendants, the only patent that could give Janssen the protection afforded by the 30-month stay was the '438 patent.

168. Consequently, after the '213 patent expired, the 30-month stay remained in effect only because of Janssen's strategic and unlawful decision to continue prosecuting its case as to the '438 patent (which Janssen knew to be invalid).

169. Janssen's decision to lump all of the generic ANDA filers in a single lawsuit asserting both the '213 and '438 patent does not change the sham nature of the claims it initially asserted against the ten generic manufacturers who had not served P.IV certifications as to the '213 patent. Nor does it insulate the sham nature of the claims it later maintained against all eleven generic manufacturers after the expiration of the '213 patent.

---

<sup>26</sup> Due to the NCE exclusivity provisions discussed above, the "30-month stay" as to the '438 patent actually lasted until October 27, 2018.

**2. December 2015: Generic companies ask the PTAB to assess the validity of the '438 patent.**

170. On December 4, 2015, Amerigen Pharmaceuticals Limited (Amerigen) filed a petition for *inter partes* review of the '438 patent with the PTAB. Amerigen requested cancellation of all 20 claims of the '438 patent, arguing that (a) claims 1-20 were obvious over O'Donnell (2004) in view of a 1990 article by G.S. Gerber and G.W. Chodak,<sup>27</sup> and (b) claims 1-4 and 6-11 were obvious over the '213 patent in view of Gerber (1990).

171. Amerigen began by pointing out the strong evidence that the claimed invention of the '438 patent was, as the PTO held, obvious. As Amerigen noted, the prior art taught the use of abiraterone acetate as an effective anti-cancer agent which suppresses testosterone synthesis in prostate cancer patients. And while it was known that suppressing testosterone synthesis was beneficial to treating prostate cancer, it was also known that using a CYP17 inhibitor to reduce testosterone synthesis also undesirably suppressed the production of cortisol, a glucocorticoid. So, the prior art also taught that concomitant glucocorticoid replacement therapy might be necessary when administering abiraterone acetate (as was common practice when administering ketoconazole, another CYP17 inhibitor). The prior art also taught that abiraterone acetate was a more effective CYP17 inhibitor than ketoconazole. Finally, the prior art taught that the combination of ketoconazole and prednisone was a safe and effective treatment for refractory metastatic prostate cancer.

---

<sup>27</sup> Gerber, G.S. & Chodak, G.W., *Prostate specific antigen for assessing response to ketoconazole and prednisone in patients with hormone refractory metastatic prostate cancer*, 144 J. Urol. 1177-79 (1990) (Gerber 1990).

172. Amerigen noted that based on the teachings of prior publications including the '213 blocking patent, a POSA would have combined abiraterone acetate and prednisone with a reasonable expectation of success.

173. Amerigen went on to explain why “secondary considerations” were insufficient to overcome that finding. In particular, Amerigen pointed out that evidence of secondary considerations, such as commercial success, is only relevant if the patentee can show a direct link, or “nexus,” between the secondary consideration and the claims of the patent. But any commercial success of Zytiga was due to the effectiveness of abiraterone acetate in treating prostate cancer, not the subject matter of the '438 patent (*i.e.*, the combination of abiraterone acetate and prednisone).

174. Amerigen noted that Janssen had presented zero evidence to the PTO suggesting that it was the claimed invention, rather than abiraterone acetate itself, that was responsible for any commercial success. “Instead, [Janssen] mislead the Examiner by arguing that because Zytiga is approved in combination with prednisone, Zytiga is a commercial embodiment of the claimed invention.”

175. Amerigen pointed to Janssen’s failure to provide any evidence of unexpected results or to any showing that the claimed invention satisfied any long-felt but unmet need.

176. Finally, Amerigen pointed out that both abiraterone acetate and its use for the treatment of cancer are claimed in the '213 patent and the existence of this “blocking patent” acted to limit the ability of any would-be competitors to develop a competing product.

**G. 2016: The PTAB accepts Amerigen’s petition (making its first determination that the claims of the ’438 patent were likely too obvious to be patented), more generics file petitions for *inter partes* review, and the ’213 patent expires.**

**1. Early summer 2016: Ten more generics file petitions for *inter partes* review to invalidate the ’438 patent as the PTAB initiates a formal review.**

177. On May 31, 2016, the PTAB granted Amerigen’s petition and instituted a formal proceeding to examine the ’438 patent. The PTAB grants petitions for *inter partes* review only where the challenger of the patent shows “a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”<sup>28</sup>

178. In so doing, the PTAB adopted Janssen’s lexicography and interpreted certain claims terms:

<b>Claim term(s)</b>	<b>PTAB construction</b>
“treat,” “treating,” and “treatment”	include the eradication, removal, modification, management or control of a tumor or primary, regional, or metastatic cancer cells or tissue and the minimization or delay of the spread of cancer
“anti-cancer agent”	any therapeutic agent that directly or indirectly kills cancer cells or directly or indirectly prohibits, stops or reduces the proliferation of cancer cells
“refractory cancer”	cancer that is not responding to an anticancer treatment or cancer that is not responding sufficiently to an anti-cancer treatment

179. In finding a reasonable likelihood that Amerigen would prevail on obviousness, the PTAB noted that O’Donnell (2004) suggests the co-administration of a glucocorticoid (such as prednisone), Gerber (1990) discloses co-administration of prednisone with ketoconazole, and ketoconazole and abiraterone acetate were both known CYP17 inhibitors. Likewise, the PTAB noted that the ’213 patent (sometimes referred to in the PTAB proceedings as Barrie (2004))

---

<sup>28</sup> 35 U.S.C. § 314(a).

discloses the use of abiraterone acetate for treating prostate cancer and contrasts that with the performance of ketoconazole.

180. On June 29, 2016, Argentum sought *inter partes* review of the '438 patent. Concurrently with its petition, Argentum filed a motion seeking to join its case with the one filed by Amerigen.<sup>29</sup> The Amerigen and Argentum petitions were eventually consolidated.

181. On June 30, 2016, Mylan sought *inter partes* review of the '438 patent, raising many of the same points that had been made by Amerigen, and seeking cancellation on the same grounds (obviousness over O'Donnell (2004) in view of Gerber (1990) and obviousness over the '213 patent in view of Gerber (1990)). Shortly thereafter, a group of petitioners including Actavis, Amneal, Dr. Reddy's, Sun, Teva, West-Ward, and Hikma filed a petition on the same grounds, and sought joinder with the Mylan IPR. A few months later, Wockhardt filed an *inter partes* review petition also challenging the '438 patent.

182. All of these petitions raised the same basic arguments that had been raised in the Amerigen petition. And all would be accepted by the PTAB.

**2. August 2016: Actavis changes its P.IV certification on the '213 blocking patent to a P.III certification, and any semblance of legitimacy to Janssen's litigation disappears.**

183. On August 30, 2016, Actavis, Janssen, and BTG filed a joint stipulation indicating that Actavis had changed its P.IV certification on the '213 blocking patent to a P.III certification. In so doing, Actavis certified to the FDA that it would not be seeking to sell its generic abiraterone acetate product prior to the December 13, 2016 expiration of the '213 blocking patent.

---

<sup>29</sup> On September 19, 2016, the PTAB accepted Argentum's petition and granted the motion to join the proceeding with the Amerigen action.

184. In light of the P.III certification, Actavis, Janssen and BTG all agreed “that a case or controversy no longer exists between them with respect to the ’213 patent” and “all claims, counterclaims, and affirmative defenses relating to the ’213 patent are dismissed, without prejudice, for lack of subject matter jurisdiction.”

185. From this point forward, Janssen and BTG’s prosecution of the litigation was solely based on its assertion of the ’438 patent which, they both knew, was invalid.

**3. Late 2016: Judge McNulty issues his *Markman* decision, adopting Janssen’s narrow definition of “treatment” and “treating” and the ’213 patent expires.**

186. By late 2016, the parties in patent litigation over the ’438 patent had proceeded to the claim construction phase, wherein the court construes any disputed terms.

187. In a *Markman* decision entered November 10, 2016, Judge McNulty construed the terms “treated” and “treating,” interpreting them as follows:

Claim term(s)	Judge McNulty construction
“treating” and “treatment”	the eradication, removal, modification, management or control of a tumor or primary, regional, or metastatic cancer cells or tissue and the minimization or delay of the spread of cancer

188. This was narrower than the PTAB construction of the same terms; the PTAB definition began with the word “include” and thus did not limit the definition to the listed items.

189. On December 13, 2016, the ’213 blocking patent expired.

**H. 2017: The PTAB grants additional petitions for *inter partes* review, Janssen and BTG continue their baseless litigations, and generic companies clear regulatory hurdles.**

190. In 2017, movement continued on various fronts. The PTAB accepted for *inter partes* review two more petitions challenging all of the claims of the ’438 patent. In the meantime, Janssen and BTG continued to pursue litigation against multiple generic

manufacturers on the grounds that they were infringing the '438 patent. And the FDA began to grant tentative approval to several potential generic competitors.

191. On January 10, 2017, the PTAB determined that Mylan's petition warranted institution of *inter partes* review of claims 1-20 of the '438 patent. The PTAB did not join Mylan's petition with the Amerigen/Argentum proceeding already underway.

192. On April 12, 2017, the PTAB accepted the petition filed by Actavis and others, joining it with the pending Mylan petition.

193. On the litigation front, Janssen and BTG filed an amended complaint on January 30, 2017. The amended complaint reasserted claims relating to the '213 blocking patent; this despite the facts that (a) the '213 blocking patent had expired more than a month earlier and (b) Janssen and BTG had agreed almost a year earlier in a stipulation with Actavis that there was no case or controversy as to the '213 blocking patent.

194. Later in the year, on August 25, 2017, Janssen and BTG filed suit against Teva, asserting infringement of the '438 patent in connection with Teva's submission of an ANDA seeking approval to launch a generic version of 500 mg tablets of abiraterone acetate. This case was subsequently consolidated into the pending action before Judge McNulty.

195. By shortly thereafter, in October 2017, at least two generics received tentative approvals from the FDA for their abiraterone acetate ANDAs. Absent the litigation filed by Janssen and BTG, these tentative approvals would have been final approvals.

196. On October 18, 2017, the FDA granted tentative approval to Wockhardt for its abiraterone acetate ANDA, No. 208380.

197. On October 27, 2017, the FDA granted tentative approval to Amneal for its abiraterone acetate ANDA, No. 208327.

198. Both tentative approval letters noted the existence of the Orange Book-listed '438 patent, and the litigation that had been filed by Janssen and BTG, noting that final approval could not be granted until:

1. a the expiration of the 7.5-year time period provided for in sections 505(j)(5)(B)(iii) and 505(j)(5)(F)(ii) of the FD&C Act,
  - b. the date the court decides that the '438 patent is invalid or not infringed (see section 505(j)(5)(B)(iii)(I), (II), and (III) of the FD&C Act), or
  - c. the '438 patents [sic] has expired, and
2. The Agency is assured that there is no new information that would affect whether final approval should be granted.

199. The FDA's letters make clear that both Wockhardt and Amneal were prevented from receiving final approval in October 2017 due to the litigation that Janssen and BTG had filed and were continuing to pursue concerning the '438 patent.

**I. Early 2018: The PTAB issues three decisions, each finding the '438 patent invalid as obvious.**

**1. January 17, 2018: The PTAB issues its first decision finding the claims of the '438 patent unpatentable.**

200. On January 17, 2018, the PTAB issued two final written decisions, one in the Amerigen/Argentum matter and one in the Mylan matter, both concluding that all claims of the '438 patent were invalid. The PTAB's reasoning in these two decisions was substantially similar.

201. The PTAB noted Judge McNulty's claim construction decision, but elected to continue with its initial interpretation of the key claims terms (including the broader definition of "treat"), to which Janssen did not object:

Claim term(s)	PTAB Construction
“treat,” “treating,” and “treatment”	Include the eradication, removal, modification, management or control of a tumor or primary, regional, or metastatic cancer cells or tissue and the minimization or delay of the spread of cancer
“anti-cancer agent”	Any therapeutic agent that directly or indirectly kills cancer cells or directly or indirectly prohibits, stops or reduces the proliferation of cancer cells
“refractory cancer”	Cancer that is not responding to an anti-cancer treatment or cancer that is not responding sufficiently to an anti-cancer treatment
“therapeutically effective amount of prednisone”	An amount of prednisone effective for treating prostate cancer.

202. Turning to the substance of the parties’ arguments, the PTAB rejected Janssen’s argument that POSAs considered the prior art teachings about ketoconazole to be irrelevant to abiraterone, along with Janssen’s related suggestion that POSAs were unmotivated to combine abiraterone with a glucocorticoid. Noting that the ’438 specification described administering abiraterone with “at least one additional therapeutic agent, such as an anti-cancer agent or a steroid,” the PTAB concluded that a POSA would have reasonably expected success in using prednisone. The specification’s defining prednisone as both an “anti-cancer agent” and a “steroid” demonstrated that prednisone was expected to have therapeutic effects even apart from anti-cancer effects.

203. The PTAB began by addressing the generic manufacturers’ argument that it was obvious to use a glucocorticoid, such as prednisone, to reduce the undesirable effects of administering a CYP17 inhibitor to reduce testosterone synthesis, including the suppressed production of cortisol, a glucocorticoid, which lead to increased ACTH production.

204. In support, the generic manufacturers cited O’Donnell (2004), which taught, *inter alia*, that abiraterone acetate was more effective than ketoconazole in suppressing testosterone levels, and Gerber (1990), which taught, *inter alia*, that the combination of ketoconazole and

prednisone is safe and effective in treating humans with hormone-refractory advanced prostate cancer. The generic manufacturers also cited Barrie (2004) – the '213 blocking patent – which, like O'Donnell (2004), taught, *inter alia*, that abiraterone acetate is more effective than ketoconazole in suppressing testosterone levels in mammals *in vitro*. In light of O'Donnell (2004)/Gerber (1990) and Barrie (2004)/Gerber (1990), it would have been obvious to one skilled in the art to combine abiraterone acetate and prednisone with a reasonable expectation of success.

205. As had examiner Hui at the PTO, the PTAB rejected each of Janssen's responsive arguments on obviousness.

206. First, the PTAB rejected Janssen's argument that because abiraterone acetate and ketoconazole have different effects on steroid biosynthesis and different side effects, one skilled in the art would not have used the example of ketoconazole's clinical use to take investigative steps with abiraterone acetate. The PTAB, while acknowledging differences in the specific mechanism by which abiraterone acetate and ketoconazole functioned, concluded that "one of ordinary skill in the art would look to the administration of ketoconazole for guidance on how to administer abiraterone acetate."

207. Second, the PTAB rejected Janssen's argument that O'Donnell (2004) did not establish a need for glucocorticoid replacement with abiraterone acetate, agreeing with the generic manufacturers' "plain reading of O'Donnell (2004) as indicating further investigation of the necessity of co-administration of a glucocorticoid with abiraterone acetate."

208. Third, the PTAB rejected Janssen's argument that ketoconazole plus prednisone was not known to be "safe and effective" for prostate cancer in 2006, noting that Gerber (1990)

was a peer-reviewed article published in a reputable journal and O'Donnell (2004) corroborates that the clinical use of ketoconazole is "common practice."

209. Fourth, the PTAB rejected Janssen's argument that prednisone's side effects would have dissuaded a person from using it without a clear clinical benefit, pointing out that while glucocorticoids have certain risks, they did not outweigh the positive effects in seriously ill patients with limited life expectancy.

210. Fifth, the PTAB rejected Janssen's argument that in 2006, prednisone was not known to have anti-cancer effects. Construing the term "therapeutically effective amount of prednisone" as "an amount of prednisone effective for treating prostate cancer" and recognizing that "treating" can include a number of actions, the PTAB concluded that prior art provides a reasonable expectation that prednisone could be used as a therapeutic agent in the treatment of prostate cancer.<sup>30</sup>

211. Sixth, the PTAB rejected Janssen's argument that the prior art provided no basis to expect that prednisone would provide anti-prostate cancer effects, for the same basic reasons it rejected Janssen's fifth argument.

212. Seventh, the PTAB rejected Janssen's contention that the generic manufacturers were relying on hindsight, noting that prior research did focus on use of a CYP17 inhibitor with glucocorticoids to treat prostate cancer.

---

<sup>30</sup> This claim construction was broader than the construction adopted by Judge McNulty in his 2016 *Markman* opinion. However, any difference in construction is immaterial to the obviousness analysis. In his final opinion, Judge McNulty noted studies finding glucocorticoids alone may have antitumor effects, and also found the palliative effects of prednisone would have provided some of the motivation to combine it with abiraterone acetate.

213. Eighth, the PTAB rejected Janssen's argument that there was no motivation to combine abiraterone acetate with prednisone, finding that none of the prior art taught away from, and instead encouraged, doing exactly that.

214. Next, the PTAB addressed the secondary considerations that Janssen posited to overcome the clear obviousness, specifically rejecting all four, including the alleged "commercial success" argument that Janssen had used to dupe examiner Hui.

215. The PTAB found no unexpected results, determining there was insufficient evidence of the allegedly unexpected results and noting that in any event, Janssen failed to tie those results to the administration of abiraterone acetate and prednisone.

216. The PTAB rejected the "skepticism and failure of others" argument noting, among other things, that Janssen's arguments were all directed solely to abiraterone acetate (not the combination of abiraterone acetate and prednisone). And the PTAB noted that abiraterone acetate itself had been previously patented, demonstrating that at least some had overcome any skepticism.

217. The PTAB found that any "long felt need" was, at best, neutral. Of course, any drug that improves cancer patient survival rates will nearly always satisfy a need. But abiraterone acetate's availability for nearly a decade before the issuance of the '438 patent undermined Janssen's argument.

218. Finally, the PTAB turned to the "commercial success" argument – *i.e.*, the specific basis upon which Janssen had first obtained the '438 patent.

219. The PTAB began by noting there was no dispute that Zytiga is commercially successful in term of dollar sales, although it stressed that abiraterone acetate was previously known and patented before the '438 patent issued. The PTAB was persuaded by the generic

manufacturers’ “argument that the blocking patent would have deterred others from exploring the commercial potential of abiraterone acetate, and thus, that blocking patent to abiraterone acetate limits the applicability of other evidence of commercial success.”

220. The PTAB also credited the generic manufacturers’ argument that there was no nexus between the commercial success of Zytiga and the claimed invention of the ’438 patent, as the record, including Janssen’s own prescribing literature, demonstrated that Zytiga’s anti-cancer effects come from abiraterone acetate.

**2. January 17, 2018: The PTAB issues its second decision finding the claims of the ’438 patent unpatentable.**

221. On the same day that it issued its decision in the Amerigen and Mylan proceedings, the PTAB issued a final written decision in the Wockhardt proceeding. The Wockhardt decision addressed obviousness over the combination of Gerber (1990), O’Donnell (2004) and Sartor (1998), a different combination of prior art than Amerigen and Mylan had relied upon.

222. The PTAB once again found the claims of the ’438 patent invalid as obvious. In addition to the O’Donnell (2004) and Gerber (1990) references that the PTAB relied on in the Amerigen/Mylan decision, the PTAB highlighted the Sartor (1998) reference as another, independent basis, for concluding that the claims of the ’438 patent were obvious. Sartor (1998), recognized by the PTAB as a peer-reviewed article published in a reputable journal, disclosed that the administration of prednisone alone demonstrated some degree of success in a group of patients, and indicated some measure of efficacy for certain mCRPC patients.

223. As with the Amerigen and Mylan petitions, the PTAB rejected Janssen’s non-obviousness arguments as weak and unsupported. In so doing, it reiterated that both abiraterone and prednisone were known in the prior art and that Janssen’s assertion that the combination of

the two drove Zytiga's sales failed to demonstrate a nexus between commercial success and the claimed invention.

224. On February 16, 2018, Janssen filed a request for rehearing on the petitions.

**J. Mid 2018: Following a nine-day trial, Judge McNulty finds clear and convincing evidence that the '438 patent is invalid.**

225. Apotex was the only generic manufacturer named in the Janssen/BTG litigation that had not filed, or joined, any of the PTAB petitions. As such, Apotex possessed something no other generic did at the time: the unquestioned ability to challenge the validity of the '438 patent at the upcoming trial in the district court.

226. Apotex's unique status came from 35 U.S.C. § 315(e)(2), an estoppel provision providing that a party who seeks review of a patent claim before the PTAB that leads to a written decision from the PTAB may not pursue an invalidity argument in the district court on the same grounds that it had presented to the PTAB.

227. It is an open question as to whether this provision prevents *successful* PTAB petitioners (such as the non-Apotex generics here) from pursuing an invalidity defense in the district court. But since Apotex had not filed or joined any of the petitions decided by the PTAB, there was no question that Apotex was free to pursue any and all invalidity defenses in the district court.

228. Desperate to avoid a judicial decision invalidating the '438 patent, on top of the three PTAB decisions invalidating it, Janssen and BTG settled with Apotex on April 20, 2018, entering into a license agreement for the '438 patent and dismissing Apotex from the action.

229. With Apotex dismissed, Janssen and BTG filed a motion *in limine* based on the language of § 315(e)(2) seeking to prevent the generic defendants from raising at trial the very invalidity defenses on which they had prevailed at the PTAB. Janssen and BTG argued that

Judge McNulty must ignore the invalidity determinations of the PTAB and enforce the '438 patent without any examination of its merits.

230. Saving the '438 patent was not the goal. Janssen and BTG were simply trying to further delay generic competition, which they could do so long as they avoided a determination on the merits – and another repudiation of the '438 patent.

231. On July 23, 2018, Judge McNulty commenced what would be a nine-day trial, concluding on August 2, 2018. Between August 31, 2018 and September 21, 2018, the parties submitted their post-trial briefings.

232. On October 26, 2018, Judge McNulty issued his opinion, finding, *inter alia*, that the generic defendants had met their burden of proving, by clear and convincing evidence, that the '438 patent is invalid on obviousness grounds.

233. Judge McNulty began his analysis by dispensing with Janssen's argument that the district court lacked subject matter jurisdiction to decide invalidity. While noting that the literal language of 35 U.S.C. § 315(e)(2) could be read in the manner proposed by Janssen, he concluded that doing so would fly in the face of the statute's intent, which is "to prevent parties from using multiple, possibly inconsistent and wasteful means of attacking a patent." Judge McNulty refused to "accept, however, that Congress intended to require a party to stand mute in court because it previously prevailed on the same issue before the PTAB. The result would be a decision reached without consideration of legally relevant facts and issues."

234. Judge McNulty pointed out the perverse result that Janssen's argument could lead to: "this Court could find itself in the position of being required to enter an injunction against infringement based on a patent already found invalid."

235. As for obviousness, Judge McNulty found, just as examiner Hui and the PTAB had, that the combination therapy claimed in the '438 patent would have been obvious to a POSA. He noted that abiraterone had been identified in the prior art as a second-line prostate cancer treatment that was regarded as superior to ketoconazole, and that there was more than sufficient motivation to combine abiraterone acetate with prednisone. In fact, the prior art went so far as to identify specific dosages of prednisone (between 10 and 20 mg) to use.

236. The secondary considerations raised by Janssen and BTG did not alter his conclusion on obviousness. Chief among the reasons for this was the fact of the '213 blocking patent. Just like the PTAB had concluded the existence of the '213 blocking patent cast serious doubt on Janssen and BTG's claims of commercial success (and examiner Hui would have reached the same conclusion if she had been informed of the '213 blocking patent), Judge McNulty noted that the sales of Zytiga may not be entirely attributable to the combination therapy claimed in the '438 patent.<sup>31</sup>

237. In his accompanying order, Judge McNulty noted that the 30-month stay (as extended by the NCE exclusivity provision) was set to expire on Sunday, October 28, 2018. Based on his preliminary assessment that the case presented a potentially appealable issue relating to the PTAB estoppel issue, Judge McNulty entered an order for expedited briefing on the appropriateness of a stay pending appeal. He also found that a "very brief" temporary stay to maintain the status quo through October 30, 2018 was warranted and prevented any generic from launching prior to October 31, 2018.

---

<sup>31</sup> Judge McNulty also assessed the parties' infringement contentions, finding that if the patent had been valid, the generic products would have infringed it.

**K. Late 2018 and early 2019: After losing at the district court, Janssen and BTG continue trying to delay generic competition, the courts rebuff them at every turn, and generic competition for Zytiga finally begins.**

238. Following Judge McNulty's ruling on invalidity, Janssen used every procedural move it could think of to try and delay generic entry. All, however, proved unsuccessful as both the Federal Circuit and Supreme Court quickly disposed of Janssen's emergency motions for a stay.

239. On October 30, 2018, Judge McNulty heard argument on Janssen's motion and briefly extended his temporary injunction until the earlier of November 9, 2018 or the Federal Circuit's ruling on Janssen's request for an injunction pending appeal.

240. On October 31, 2018, the very first day after the 30-month stay expired, the FDA granted final approval to at least four generic manufacturers' abiraterone acetate ANDAs – Apotex, Hikma, Mylan, and Teva. At that point, they remained blocked from launching only by the temporary injunction.

241. On November 1, 2018, Janssen and BTG filed an emergency motion before the Federal Circuit, seeking an injunction pending appeal, arguing that the “most fundamental[]” error committed by Judge McNulty was his decision to actually examine the validity of the '438 patent. (Of course, the entire PTAB estoppel issue was nothing but another delay tactic. Even if Janssen were to ultimately prevail on that procedural point, it would not be a ‘merits based’ victory. Instead, it would simply serve to prolong the inevitable – the Federal Circuit's confirmation that the '438 patent is invalid for obviousness.)

242. On November 20, 2018, the Federal Circuit rejected Janssen's request for injunctive relief, concluding “based on the papers submitted that [Janssen and BTG] have not established that an injunction is warranted here” and denying the motion for an injunction and

vacating the temporary injunction. The Federal Circuit also set a merits briefing schedule and invited the Director of the PTO to submit his views on the PTAB estoppel issues.

243. Later that evening, Janssen filed an emergency motion to reinstate the temporary injunction pending a further appeal to the Supreme Court. The Federal Circuit denied this motion the following morning.

244. On November 21, 2018 Janssen and BTG filed an application for injunctive relief pending appeal with the United States Supreme Court. The Supreme Court denied Janssen's request for injunctive relief pending appeal.

245. Immediately following the Federal Circuit's rejection of Janssen's and BTG's emergency motion, generic competition for Zytiga began. On or about November 21, 2018, Mylan and Teva each launched 250 mg generic abiraterone acetate products. Hikma/West-Ward and Apotex each launched on November 23, 2018. Janssen itself then launched an authorized generic version of Zytiga.

246. On or about January 7, 2019, Amneal launched its generic product and Wockhardt launched its generic product on or about February 27, 2019.

247. The Federal Circuit consolidated Janssen's appeals of the three PTAB decisions and the district court decision. On January 18, 2019, Janssen and BTG filed their opening appellate brief. The generic defendants filed their opposition on February 19, 2019, and briefing on the appeal was completed on February 28, 2019 when Janssen and BTG filed their reply brief.

248. Oral argument on the consolidated appeal was held on March 14, 2019.

**L. Absent the sham litigations, one or more Zytiga generics could have been available in December 2016, and would have been available no later than November 2017.**

249. Had Janssen and BTG not asserted the '438 patent in litigation against their generic competitors, there would have been no 30-month stay on FDA approval for 10 of the 11

first-to-file ANDA applications. And once the '213 blocking patent expired on December 13, 2016, there would have been no “exclusivity” preventing any of the 11 generics from coming on the market.

250. Absent Janssen and BTG’s assertion of the ’438 patent, generic competition for Zytiga would have begun as early as December 2016, when the ’213 patent expired, and no later than October 2017. And once generic competition entered the market, Janssen would have launched an authorized generic (as it did in November of 2018), thereby bringing even more competition to the market and further driving down the cost of those purchasing Zytiga.

251. While the full effect of Janssen and BTG’s conduct will be the subject of discovery, absent the sham litigation over the ’438 patent, other generic manufacturers might have altered their ANDA activities so as to be in a position to receive final approval in the fall of 2017 around the same time as Mylan, Teva, and others.

**M. Janssen possesses monopoly power over abiraterone acetate.**

252. At all relevant times, Janssen has maintained monopoly power over abiraterone acetate: it had the power to raise and/or maintain the price of abiraterone acetate at supra-competitive levels without losing substantial sales.

253. To the extent that the plaintiffs and the class are required to prove monopoly power circumstantially by first defining a relevant product market, the plaintiffs allege that the relevant product market is Zytiga and therapeutically equivalent (“AB-rated”) abiraterone acetate generics.

254. Through the sale of Zytiga, Janssen has had a one hundred percent (100%) market share in the relevant market at all times.

255. Prior to the late 2018 generic entrants discussed above, there were no generic competitors to Zytiga and there are no other reasonably interchangeable drug products available

to prescribing physicians at the dosages at, and for the indications for which, Zytiga is prescribed.

256. Given the nature of the relevant market, Janssen needed to control *only* Zytiga and therapeutically equivalent generics of Zytiga—and no other products—to maintain the price of Zytiga profitably at supra-competitive levels.

257. Janssen used its market power to maintain premium pricing for Zytiga since the drug's inception. At all times, Janssen sold branded Zytiga well in excess of both marginal cost and of the competitive price, and has enjoyed unusually high profit margins. Zytiga is extremely expensive, with an average monthly wholesale price of approximately \$3,000.

258. Only the market entry of a competing, therapeutically equivalent generic version of Zytiga would make Janssen unable to profitably maintain its prices for Zytiga without losing substantial sales. However, the FDA's approval process for NDAs serves as a significant barrier to new drug entry into this market. The only feasible way for a generic competitor to enter this market requires obtaining a sample of Zytiga, but Janssen has complete control over its distribution.

259. Janssen has used its market power to foreclose or otherwise adversely affect competition in the market for FDA-approved abiraterone acetate drug products by—among other unlawful tactics—preventing potential competitors from obtaining samples and active pharmaceutical ingredient (“API”) supplies, which are necessary for formulating a generic version of the drug. This conduct has caused output to be artificially low, raised competitors' costs, and/or kept the market price for FDA-approved abiraterone acetate artificially high.

260. Janssen's conduct has forced consumers who need abiraterone acetate to purchase Zytiga at artificially high and noncompetitive price levels and denied those consumers the

availability of a lower cost generic abiraterone acetate product. Going forward, consumers who need abiraterone acetate will be forced to purchase Zytiga at artificially high and noncompetitive prices and will be denied the availability of a lower cost generic abiraterone acetate product.

261. Janssen has had a significant incentive to maintain its monopoly over abiraterone acetate and keep prices artificially high. Zytiga has been a blockbuster drug for Janssen. Sales of Zytiga have accounted for a large majority of the company's revenues. In the first nine months of 2012, Janssen's combined worldwide sales of Zytiga were approximately \$1.2 billion. Analysts following Janssen's stock have warned that loss of its monopoly over abiraterone acetate without a follow-up product to take its place could be financially ruinous for the company.

262. The relevant geographic market is the United States and its territories.

263. At all relevant times, Janssen enjoyed high barriers to entry with respect to the above-defined relevant market.

264. A small but significant, non-transitory price increase to Zytiga by Janssen would not have caused a significant loss of sales to other drugs or products used for similar purposes, with the exception of therapeutically equivalent generic versions of abiraterone acetate, had any been available.

265. Abiraterone acetate does not exhibit significant, positive cross-price elasticity of demand with any other CYP17 inhibitor used for treating prostate cancer, but it would likely exhibit significant, positive cross-price elasticity of demand with AB-rated generic versions of Zytiga.

## **VIII. CLASS ACTION ALLEGATIONS**

266. The plaintiffs bring this action on their own behalf and on behalf of all others similarly situated as a class action under Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure, seeking damages pursuant to the common law of unjust enrichment and the antitrust,

unfair competition, and consumer protection laws of the states listed below (the “Indirect Purchaser States”), and as representative of a class defined as follows:

All persons and entities in the Indirect Purchaser States and territories who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price of Zytiga or abiraterone acetate, other than for resale, at any time during the period from December 13, 2016 through and until the anticompetitive effects of the defendants’ challenged conduct cease (the “Class Period”).

267. Excluded from the class are:

- a. the defendants and their counsel, officers, directors, management, employees, subsidiaries, and affiliates;
- b. all federal governmental entities;
- c. all persons or entities who purchased Zytiga for purposes of resale;
- d. fully insured health plans (*i.e.*, health plans that purchased insurance from another third-party payor covering 100 percent of the plan’s reimbursement obligations to its members);
- e. any “flat co-pay” consumers whose purchases of Zytiga were paid in part by a third-party payor and whose co-payment was the same regardless of the retail purchase price;
- f. pharmacy benefit managers; and
- g. all judges assigned to this case and any members of their immediate families.

268. Members of the class are so numerous and widely geographically dispersed throughout the United States and its territories that joinder is impracticable. The plaintiffs believe that the class numbers in the dozens at least and is geographically spread across the nation. Further, the identities of members of the class will be readily identifiable from information and records in the possession of Janssen.

269. The plaintiffs’ claims are typical of the claims of members of the class. The plaintiffs and all members of the class were damaged by the same wrongful conduct by Janssen,

and all paid artificially inflated prices for Zytiga and were deprived of the benefits of competition from less expensive generic versions as a result of the defendants' conduct.

270. The plaintiffs will fairly and adequately protect and represent the interests of the class. The plaintiffs' interests are coincident with, and not antagonistic to, the class.

271. The plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action litigation, and who have particular experience with class action litigation involving the pharmaceutical industry.

272. Questions of law and fact common to members of the class predominate over questions, if any, that may affect only individual class members, because the defendants have acted on grounds generally applicable to the entire class. Such generally applicable conduct is inherent in the defendants' wrongful conduct.

273. Any plaintiff who was forced to pay a higher price in the absence of generic competition has a substantial and shared interest in proving that the higher price was the result of unlawful monopolizing conduct that is redressable by an award of damages.

274. Questions of law and fact common to the class include:

- a. whether Janssen unlawfully maintained monopoly power through all or part of its overarching scheme;
- b. whether Janssen and BTG's anticompetitive scheme suppressed generic competition to Zytiga;
- c. as to those parts of Janssen and BTG's challenged conduct for which such justifications may be offered, whether there exist cognizable, non-pretextual procompetitive justifications, which defendants' challenged conduct was the least restrictive means of achieving, that offset the harm to competition in the markets in which abiraterone acetate is sold;
- d. whether direct proof of Janssen's monopoly power is available, and if available, whether it is sufficient to prove Janssen's monopoly power without the need to also define a relevant market;
- e. to the extent a relevant market or markets must be defined, what that definition is or those definitions are;

- f. determination of a reasonable estimate of the amount of delay the defendants' unlawful monopolistic, unfair and unjust conduct caused;
- g. whether the defendants' scheme, in whole or in part, has substantially affected interstate commerce;
- h. whether the defendants' scheme, in whole or in part, caused antitrust injury to the business or property of the plaintiffs and members of the class in the nature of overcharges; and
- i. the quantum of overcharges paid by the class in the aggregate.

275. Class action treatment is a superior method for the fair and efficient adjudication of this controversy. Among other things, class treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

276. The plaintiffs know of no difficulty to be encountered in the maintenance of this action that would preclude their maintenance as a class action.

## **IX. CLAIMS FOR RELIEF**

### **VIOLATIONS OF STATE ANTITRUST LAWS**

277. The plaintiffs incorporate by reference the allegations in the preceding paragraphs.

278. Beginning at a time currently unknown to the plaintiffs, but at least as early as July 2015, and continuing through the present, the exact dates being unknown to the plaintiffs, the defendants entered into continuing agreement(s), understanding(s), and conspiracy(ies) in restraint of trade artificially to fix, raise, stabilize, and peg prices for abiraterone acetate in the United States, in violation of the laws enumerated below.

279. In formulating and carrying out the alleged agreement, understanding, and conspiracy, the defendants, acting in concert with one another, did those things that they combined and conspired to do, including but not limited to the acts, practices, and course of conduct set forth above.

280. The combination and conspiracy alleged herein has had the following effects, among others:

- A. Price competition in the sale of abiraterone acetate has been restrained, suppressed, and/or eliminated in the United States;
- B. Prices for abiraterone acetate have been fixed, raised, maintained and stabilized at artificially high, non-competitive levels throughout the United States; and
- C. Those who purchased abiraterone acetate indirectly from defendants have been deprived of the benefits of free and open competition.

281. The plaintiffs and members of the class have been injured and will continue to be injured in their businesses and property by paying more for abiraterone acetate purchased indirectly from the defendants than they would have paid and will pay in the absence of the combination and conspiracy.

282. The following claims for relief one through twenty-eight are pleaded under the antitrust laws of each State or jurisdiction identified below, on behalf of the class, and arise from the defendants' exclusionary, anticompetitive scheme designed to create and maintain a monopoly for abiraterone acetate and its generic substitutes.

283. Through its anticompetitive overarching scheme and conduct described more fully above, defendants willfully maintained monopoly power in the relevant market using fraudulent, restrictive or exclusionary conduct, rather than by means of greater business acumen or a historic accident, and thereby injured the plaintiffs and the class. This anticompetitive

conduct was undertaken with the specific intent to maintain a monopoly in the abiraterone acetate market in the United States.

284. The defendants accomplished their goals by, *inter alia*, filing and maintaining litigation against multiple would-be generic competitors despite knowing that the ‘438 patent was invalid and could not be enforced, rendering their litigation a fraudulent attempt to prevent competition.

**FIRST CLAIM FOR RELIEF  
VIOLATION OF ARIZONA’S UNIFORM STATE ANTITRUST ACT,  
ARIZ. REV. STAT. § 44-1401, *et seq.***

285. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

286. By reason of the conduct alleged herein, defendants have violated Arizona Revised Statute § 44-1401, *et seq.*

287. Under Arizona law, “[t]he establishment, maintenance or use of a monopoly or an attempt to establish a monopoly of trade or commerce, any part of which is within this state, by any person for the purpose of excluding competition or controlling, fixing or maintaining prices is unlawful.” ARIZ. REV. STAT. § 44-1403.

288. The defendants entered into a contract, combination, or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in the abiraterone acetate market, a substantial part of which occurred within Arizona.

289. The defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the abiraterone acetate market, a substantial part of which occurred within Arizona, for the purpose of excluding competition or controlling, fixing, or maintaining prices in the abiraterone acetate market.

290. The defendants’ violations of Arizona law were flagrant.

291. The defendants' unlawful conduct substantially affected Arizona's trade and commerce.

292. As a direct and proximate cause of the defendants' unlawful conduct, the plaintiffs and members of the class have been injured in their business or property and are threatened with further injury.

293. By reason of the foregoing, the plaintiffs and members of the class are entitled to seek all forms of relief available under ARIZ. REV. STAT. § 44-1401, *et seq.*

**SECOND CLAIM FOR RELIEF  
VIOLATION OF CALIFORNIA'S CARTWRIGHT ACT,  
CAL. BUS. & PROF. CODE § 16700, *et seq.***

294. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

295. The California Business & Professions Code generally governs conduct of corporate entities. The Cartwright Act, CAL. BUS. & PROF. CODE §§ 16700-16770, governs antitrust violations in California.

296. California policy is that "vigorous representation and protection of consumer interests are essential to the fair and efficient functioning of a free enterprise market economy," including by fostering competition in the marketplace. CAL. BUS. & PROF. CODE § 301.

297. Under the Cartwright Act, indirect purchasers have standing to maintain an action based on the facts alleged in this complaint. CAL. BUS. & PROF. CODE § 16750(a).

298. A trust in California is any combination intended for various purposes, including but not limited to creating or carrying out restrictions in trade or commerce, limiting or reducing the production or increasing the price of merchandise, or preventing competition in the market for a commodity CAL. BUS. & PROF. CODE § 16720. Every trust in California is unlawful except as provided by the Code. *Id.* at § 16726.

299. The defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the abiraterone acetate market in California. As a result, California purchasers paid supra-competitive, artificially inflated prices for abiraterone acetate.

300. Members of the class purchased abiraterone acetate within the State of California during the class period. But for the defendants' conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial.

301. The defendants enacted a combination of capital, skill or acts for the purpose of creating and carrying out restrictions in trade or commerce, in violation of CAL. BUS. & PROF. CODE § 16700, *et seq.*

302. The plaintiffs and members of the class were injured in their business or property, with respect to purchases of Zytiga and its AB rated generic equivalents in California and are entitled to all forms of relief, including recovery of treble damages, interest, and injunctive relief, plus reasonable attorneys' fees and costs.

**THIRD CLAIM FOR RELIEF  
VIOLATION OF THE DISTRICT OF COLUMBIA ANTITRUST ACT,  
D.C. CODE § 28-4501, *et seq.***

303. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

304. The policy of District of Columbia Code, Title 28, Chapter 45 (Restraints of Trade) is to "promote the unhampered freedom of commerce and industry throughout the District of Columbia by prohibiting restraints of trade and monopolistic practices."

305. Members of the class purchased abiraterone acetate within the District of Columbia during the class period. But for the defendants' conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial.

306. Under District of Columbia law, indirect purchasers have standing to maintain an action under the antitrust provisions of the D.C. Code based on the facts alleged in this complaint, because “any indirect purchaser in the chain of manufacture, production or distribution of goods ... shall be deemed to be injured within the meaning of this chapter.” D.C. CODE § 28-4509(a).

307. The defendants contracted, combined or conspired to act in restraint of trade within the District of Columbia, and monopolized or attempted to monopolize the market for abiraterone acetate within the District of Columbia, in violation of D.C. CODE § 28-4501, *et seq.*

308. The plaintiffs and members of the class were injured with respect to purchases of Zytiga and its AB rated generic equivalents in the District of Columbia and are entitled to all forms of relief, including actual damages, treble damages, and interest, reasonable attorneys’ fees and costs.

**FOURTH CLAIM FOR RELIEF  
VIOLATION OF THE FLORIDA DECEPTIVE AND UNFAIR TRADE  
PRACTICES ACT,  
FLA. STAT. § 501.201, *et seq.***

309. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

310. The Florida Deceptive & Unfair Trade Practices Act, Florida Statute §§ 501.201, *et seq.* (the “FDUTPA”), generally prohibits “unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce,” including practices in restraint of trade. FLA. STAT. § 501.204(1).

311. The primary policy of the FDUTPA is “[t]o protect the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or

unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce.”

FLA. STAT. § 501.202(2).

312. The FDUTPA proscribes unfair methods of competition as illegal, and also provides that in determining what constitutes an “unfair method of competition” due consideration and weight should be given to the interpretations of the Federal Trade Commission and federal courts relating to § 5(a)(1) of the FTC Act and Section 5.1(a)(1) encompasses violations of the antitrust laws.

313. A claim for damages under the FDUTPA has three elements: (1) a prohibited practice; (2) causation; and (3) actual damages.

314. Under Florida law, indirect purchasers have standing to maintain an action under the FDUTPA based on the facts alleged in this complaint. FLA. STAT. § 501.211(a) (“anyone aggrieved by a violation of this [statute] may bring an action . . .”).

315. Members of the class purchased abiraterone acetate within the State of Florida during the class period. But for the defendants’ conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial.

316. The defendants entered into a contract, combination or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in the abiraterone acetate market, a substantial part of which occurred within Florida.

317. The defendants established, maintained or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the market for abiraterone acetate, for the purpose of excluding competition or controlling, fixing or maintaining prices in Florida at a level higher than the competitive market level, beginning at least as early as 2015 and continuing through the date of this filing.

318. Accordingly, the defendants' conduct was an unfair method of competition, and an unfair or deceptive act or practice within the conduct of commerce within the State of Florida.

319. The defendants' unlawful conduct substantially affected Florida's trade and commerce.

320. As a direct and proximate cause of defendants' unlawful conduct, plaintiff and the members of the class have been injured in their business or property by virtue of overcharges for abiraterone acetate and are threatened with further injury.

321. By reason of the foregoing, the plaintiffs and members of the class are entitled to seek all forms of relief, including injunctive relief pursuant to FLA. STAT. § 501.208 and declaratory judgment, actual damages, reasonable attorneys' fees and costs pursuant to FLA. STAT. § 501.211.

**FIFTH CLAIM FOR RELIEF  
VIOLATION OF THE HAWAII ANTITRUST ACT,  
HAW. REV. STAT. §480-3, *et seq.***

322. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

323. The defendants are "persons" within the meaning of Haw. Rev. Stat. § 480-1 *et seq.* (the "HUPUCA"). Haw.Rev.Stat. § 480-1. And the defendants' acts or practices as set forth above occurred in the conduct of trade or commerce.

324. The plaintiffs and members of the class are "consumer[s]" within the meaning of the Hawaii statute. Haw.Rev.Stat. § 480-1.

325. HUPUCA prohibits the use of any "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce."

326. Members of the class purchased abiraterone acetate within the State of Hawaii during the class period. But for the defendants' conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial.

327. The defendants entered into a contract, combination or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in the abiraterone acetate market, a substantial part of which occurred within Hawaii.

328. The defendants' unlawful conduct substantially affected Hawaii's trade and commerce.

329. As a direct and proximate cause of the defendants' unlawful conduct, the plaintiffs and members of the class have been injured in their business or property by virtue of overcharges for abiraterone acetate and are threatened with further injury.

330. By reason of the foregoing, the plaintiffs and members of the class are entitled to seek all forms of relief, including actual or statutory damages and any other relief deemed necessary or proper by the court. Haw.Rev.Stat. §§ 480-13, 480-13.5.

**SIXTH CLAIM FOR RELIEF  
VIOLATION OF THE ILLINOIS ANTITRUST ACT,  
740 ILL. COMP. STAT. ANN. 10/3(1), *et seq.***

331. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

332. The Illinois Antitrust Act, 740 ILCS 10/1, *et seq.*, aims "to promote the unhampered growth of commerce and industry throughout the State by prohibiting restraints of trade which are secured through monopolistic or oligarchic practices and which act or tend to act to decrease competition between and among persons engaged in commerce and trade . . . ." 740 ILCS 10/2.

333. Members of the class purchased abiraterone acetate within the State of Illinois during the class period. But for the defendants' conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial.

334. Under the Illinois Antitrust Act, indirect purchasers have standing to maintain an action for damages based on the facts alleged in this complaint. 740 ILCS 10/7(2).

335. The defendants made contracts or engaged in a combination or conspiracy with each other, for the purpose of fixing, controlling or maintaining prices for abiraterone acetate sold, and/or for allocating customers or markets for abiraterone acetate within the intrastate commerce of Illinois.

336. The defendants further unreasonably restrained trade or commerce and established, maintained or attempted to acquire monopoly power over the market for abiraterone acetate in Illinois for the purpose of excluding competition, in violation of 740 ILCS 10/1, *et seq.*

337. The plaintiffs and members of the class were injured with respect to purchases of Zytiga and its AB rated generic equivalents in Illinois and are entitled to all forms of relief, including actual damages, treble damages, reasonable attorneys' fees and costs.

**SEVENTH CLAIM FOR RELIEF  
VIOLATION OF THE IOWA COMPETITION LAW  
IOWA CODE § 553.1, *et seq.***

338. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

339. The Iowa Competition Law aims to "prohibit[] restraint of economic activity and monopolistic practices." Iowa Code § 553.2.

340. Members of the class purchased abiraterone acetate within the State of Iowa during the class period. But for the defendants' conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial.

341. The defendants contracted, combined or conspired to restrain or monopolize trade in the market for abiraterone acetate, and attempted to establish or did in fact establish a monopoly for the purpose of excluding competition or controlling, fixing or maintaining prices for abiraterone acetate, in violation of Iowa Code § 553.1, *et seq.*

342. The plaintiffs and members of the Iowa Class were injured with respect to purchases of Zytiga and its AB rated generic equivalents in Iowa, and are entitled to all forms of relief, including actual damages, exemplary damages for willful conduct, reasonable attorneys' fees and costs, and injunctive relief.

**EIGHTH CLAIM FOR RELIEF**  
**VIOLATION OF THE KANSAS RESTRAINT OF TRADE ACT**  
**KAN. STAT. ANN. § 50-101, *et seq.***

343. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

344. The Kansas Restraint of Trade Act aims to prohibit practices which, *inter alia*, “tend to prevent full and free competition in the importation, transportation or sale of articles imported into this state.” Kan. Stat. Ann. § 50-112.

345. Members of the class purchased abiraterone acetate within the State of Kansas during the class period. But for the defendants' conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial.

346. Under the Kansas Restraint of Trade Act, indirect purchasers have standing to maintain an action based on the facts alleged in this Complaint. Kan. Stat. Ann § 50-161(b).

347. The defendants combined capital, skill or acts for the purposes of creating restrictions in trade or commerce of abiraterone acetate, increasing the price of abiraterone acetate, preventing competition in the sale of abiraterone acetate, or binding themselves not to sell abiraterone acetate, in a manner that established the price of abiraterone acetate and

precluded free and unrestricted competition among themselves in the sale of abiraterone acetate, in violation of Kan. Stat. Ann. § 50-101, *et seq.*

348. The plaintiffs and members of the class were injured with respect to purchases of Zytiga and its AB rated generic equivalents in Kansas and are entitled to all forms of relief, including actual damages, reasonable attorneys' fees and costs, and injunctive relief.

**NINTH CLAIM FOR RELIEF  
VIOLATION OF MAINE'S ANTITRUST STATUTE  
ME. REV. STAT. ANN. TIT. 10 § 1101, *et seq.***

349. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

350. Part 3 of Title 10 the Maine Revised Statutes generally governs regulation of trade in Maine. Chapter 201 thereof governs monopolies and profiteering, generally prohibiting contracts in restraint of trade and conspiracies to monopolize trade. Me. Rev. Stat. Ann. tit. 10, §§ 1101-02.

351. Members of the class purchased abiraterone acetate within the State of Maine during the class period. But for the defendants' conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial.

352. Under Maine law, indirect purchasers have standing to maintain an action based on the facts alleged in this Complaint. Me. Rev. Stat. Ann. tit. 10, § 1104(1).

353. The defendants contracted, combined or conspired in restraint of trade or commerce of abiraterone acetate within the intrastate commerce of Maine, and monopolized or attempted to monopolize the trade or commerce of abiraterone acetate within the intrastate commerce of Maine, in violation of Me. Rev. Stat. Ann. tit. 10, § 1101, *et seq.*

354. The plaintiffs and members of the class were injured with respect to purchases of Zytiga and its AB rated generic equivalents in Maine and are entitled to all forms of relief, including actual damages, treble damages, reasonable attorneys' and experts' fees and costs.

**TENTH CLAIM FOR RELIEF**  
**VIOLATION OF THE MICHIGAN ANTITRUST REFORM ACT**  
**MICH. COMP. LAWS § 445.771, *et seq.***

355. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

356. The Michigan Antitrust Reform Act aims "to prohibit contracts, combinations, and conspiracies in restraint of trade or commerce...to prohibit monopolies and attempts to monopolize trade or commerce...[and] to provide remedies, fines, and penalties for violations of this act." Mich. Act 274 of 1984.

357. Members of the class purchased abiraterone acetate within the State of Michigan during the class period. But for the defendants' conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial.

358. Under the Michigan Antitrust Reform Act, indirect purchasers have standing to maintain an action based on the facts alleged in this complaint. Mich. Comp. Laws. § 452.778(2).

359. The defendants contracted, combined or conspired to restrain or monopolize trade or commerce in the market for abiraterone acetate, in violation of Mich. Comp. Laws § 445.772, *et seq.*

360. The plaintiffs and members of the class were injured with respect to purchases of Zytiga and its AB rated generic equivalents in Michigan and are entitled to all forms of relief, including actual damages, treble damages for flagrant violations, interest, costs, reasonable attorneys' fees, and injunctive or other appropriate equitable relief.

**ELEVENTH CLAIM FOR RELIEF  
VIOLATION OF THE MINNESOTA ANTITRUST LAW,  
MINN. STAT. § 325D.49, *et seq.* & 325D.57, *et seq.***

361. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

362. The Minnesota Antitrust Law of 1971 aims to prohibit any contract, combination or conspiracy when any part thereof was created, formed, or entered into in Minnesota; any contract, combination or conspiracy, wherever created, formed or entered into; any establishment, maintenance or use of monopoly power; and any attempt to establish, maintain or use monopoly power, whenever any of these affect Minnesota trade or commerce.

363. Members of the class purchased abiraterone acetate within the State of Minnesota during the class period. But for the defendants' conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial.

364. Under the Minnesota Antitrust Act of 1971, indirect purchasers have standing to maintain an action based on the facts alleged in this Complaint. Minn. Stat. § 325D.57.

365. The defendants contracted, combined or conspired in unreasonable restraint of trade or commerce in the market for abiraterone acetate within the intrastate commerce of and outside of Minnesota; established, maintained, used or attempted to establish, maintain or use monopoly power over the trade or commerce in the market for abiraterone acetate within the intrastate commerce of and outside of Minnesota; and fixed prices and allocated markets for abiraterone acetate within the intrastate commerce of and outside of Minnesota, in violation of Minn. Stat. § 325D.49, *et seq.*

366. The plaintiffs and members of the class were injured with respect to purchases of Zytiga and its AB rated generic equivalents in Minnesota and are entitled to all forms of relief,

including actual damages, treble damages, costs and disbursements, reasonable attorneys' fees, and injunctive relief necessary to prevent and restrain violations hereof.

**TWELFTH CLAIM FOR RELIEF  
VIOLATION OF THE MISSISSIPPI ANTITRUST STATUTE,  
MISS. CODE ANN. § 75-21-1, *et seq.***

367. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

368. Title 75 of the Mississippi Code regulates trade, commerce and investments. Chapter 21 thereof generally prohibits trusts and combines in restraint or hindrance of trade, with the aim that "trusts and combines may be suppressed, and the benefits arising from competition in business [are] preserved" to Mississippians. Miss. Code Ann. § 75-21-39.

369. Trusts are combinations, contracts, understandings or agreements, express or implied, when inimical to the public welfare and with the effect of, *inter alia*, restraining trade, increasing the price or output of a commodity, or hindering competition in the production or sale of a commodity. Miss. Code Ann. § 75-21-1.

370. Members of the class purchased abiraterone acetate within the State of Mississippi during the class period. But for the defendants' conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial.

371. Under Mississippi law, indirect purchasers have standing to maintain an action under the antitrust provisions of the Mississippi Code based on the facts alleged in this Complaint. Miss. Code Ann. § 75-21-9.

372. The defendants combined, contracted, understood and agreed in the market for abiraterone acetate, in a manner inimical to public welfare, with the effect of restraining trade, increasing the price of abiraterone acetate and hindering competition in the sale of abiraterone acetate, in violation of Miss. Code Ann. § 75-21-1(a), *et seq.*

373. The defendants monopolized or attempted to monopolize the production, control or sale of abiraterone acetate, in violation of Miss. Code Ann. § 75-21-3, *et seq.*

374. The defendants' abiraterone acetate are sold indirectly via distributors throughout the State of Mississippi. During the Class Period, Defendants' illegal conduct substantially affected Mississippi commerce.

375. The plaintiffs and members of the class were injured with respect to purchases of Zytiga and its AB rated generic equivalents in Mississippi and are entitled to all forms of relief, including actual damages and a penalty of \$500 per instance of injury.

**THIRTEENTH CLAIM FOR RELIEF  
VIOLATION OF THE MISSOURI MERCHANDISING PRACTICES ACT,  
MO. ANN. STAT. § 407.010, *et seq.***

376. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

377. Chapter 407 of the Missouri Merchandising Practices Act (the "MMPA") generally governs unlawful business practices, including antitrust violations such as restraints of trade and monopolization.

378. Members of the class purchased abiraterone acetate within the State of Missouri during the class period. But for the defendants' conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial.

379. Under Missouri law, indirect purchasers have standing to maintain an action under the MMPA based on the facts alleged in this Complaint. *Gibbons v. J. Nuckolls, Inc.*, 216 S.W.3d 667, 669 (Mo. 2007).

380. The defendants contracted, combined or conspired in restraint of trade or commerce of abiraterone acetate within the intrastate commerce of Missouri, and monopolized or attempted to monopolize the market for abiraterone acetate within the intrastate commerce of

Missouri by possessing monopoly power in the market and willfully maintaining that power through agreements to fix prices, allocate markets and otherwise control trade, in violation of Mo. Ann. Stat. § 407.010, *et seq.*

381. The plaintiffs and members of the class were injured with respect to purchases of Zytiga and its AB rated generic equivalents in Missouri and are entitled to all forms of relief, including actual damages or liquidated damages in an amount which bears a reasonable relation to the actual damages which have been sustained, as well as reasonable attorneys' fees, costs, and injunctive relief.

**FOURTEENTH CLAIM FOR RELIEF  
VIOLATION OF THE NEBRASKA JUNKIN ACT,  
NEB. REV. STAT. § 59-801, *et seq.***

382. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

383. Chapter 59 of the Nebraska Revised Statute generally governs business and trade practices. Sections 801 through 831 thereof, known as the Junkin Act, prohibit antitrust violations such as restraints of trade and monopolization.

384. Members of the class purchased abiraterone acetate within the State of Nebraska during the class period. But for the defendants' conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial.

385. Under Nebraska law, indirect purchasers have standing to maintain an action under the Junkin Act based on the facts alleged in this Complaint. Neb. Rev. Stat. § 59-821.

386. The defendants contracted, combined or conspired in restraint of trade or commerce of abiraterone acetate within the intrastate commerce of Nebraska, and monopolized or attempted to monopolize the market for abiraterone acetate within the intrastate commerce of Nebraska by possessing monopoly power in the market and willfully maintaining that power

through agreements to fix prices, allocate markets and otherwise control trade, in violation of Neb. Rev. Stat. § 59-801, *et seq.*

387. The plaintiffs and members of the class were injured with respect to purchases of Zytiga and its AB rated generic equivalents in Nebraska and are entitled to all forms of relief, including actual damages or liquidated damages in an amount which bears a reasonable relation to the actual damages which have been sustained, as well as reasonable attorneys' fees, costs, and injunctive relief.

**FIFTEENTH CLAIM FOR RELIEF  
VIOLATION OF THE NEVADA UNFAIR TRADE PRACTICES ACT,  
NEV. REV. STAT. § 598A.010, *et seq.***

388. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

389. The Nevada Unfair Trade Practice Act ("NUTPA") states that "free, open and competitive production and sale of commodities ... is necessary to the economic well-being of the citizens of the State of Nevada." Nev. Rev. Stat. Ann. § 598A.030(1).

390. The policy of NUTPA is to prohibit acts in restraint of trade or commerce, to preserve and protect the free, open and competitive market, and to penalize all persons engaged in anticompetitive practices. Nev. Rev. Stat. Ann. § 598A.030(2). Such acts include, *inter alia*, price fixing, division of markets, allocation of customers, and monopolization of trade. Nev. Rev. Stat. Ann. § 598A.060.

391. Members of the class purchased abiraterone acetate within the State of Nevada during the class period. But for the defendants' conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial.

392. Under Nevada law, indirect purchasers have standing to maintain an action under NUTPA based on the facts alleged in this Complaint. Nev. Rev. Stat. Ann. § 598A.210(2).

393. The defendants fixed prices by agreeing to establish prices for abiraterone acetate in Nevada, divided Nevada markets, allocated Nevada customers, and monopolized or attempted monopolize trade or commerce of abiraterone acetate within the intrastate commerce of Nevada, constituting a contract, combination or conspiracy in restraint of trade in violation of Nev. Rev. Stat. Ann. § 598A, *et seq.*

394. The plaintiffs and members of the class were injured with respect to purchases of Zytiga and its AB rated generic equivalents in Nevada in that at least thousands of sales of Defendants' abiraterone acetate took place in Nevada, purchased by Nevada consumers at supra-competitive prices caused by the defendants' conduct.

395. Accordingly, the plaintiffs and members of the Nevada Class are entitled to all forms of relief, including actual damages, treble damages, reasonable attorneys' fees, costs, and injunctive relief.

396. In accordance with the requirements of § 598A.210(3), notice of this action was mailed to the Nevada Attorney General by the plaintiffs.

**SIXTEENTH SIXTEENTH CLAIM FOR RELIEF  
VIOLATION OF NEW HAMPSHIRE'S ANTITRUST STATUTE,  
N.H. REV. STAT. ANN. TIT. XXXI, § 356, *et seq.***

397. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

398. Title XXXI of the New Hampshire Statutes generally governs trade and commerce. Chapter 356 thereof governs combinations and monopolies and prohibits restraints of trade. N.H. Rev. Stat. Ann. §§ 356:2, 3.

399. Members of the class purchased abiraterone acetate within the State of New Hampshire during the class period. But for the defendants' conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial.

400. Under New Hampshire law, indirect purchasers have standing to maintain an action based on the facts alleged in this Complaint. N.H. Rev. Stat. Ann. § 356:11(II).

401. The defendants fixed, controlled or maintained prices for abiraterone acetate, allocated customers or markets for abiraterone acetate, and established, maintained or used monopoly power, or attempted to, constituting a contract, combination or conspiracy in restraint of trade in violation of N.H. Rev. Stat. Ann. § 356:1, *et seq.*

402. The plaintiffs and members of the class were injured with respect to purchases of Zytiga and its AB rated generic equivalents in New Hampshire and are entitled to all forms of relief, including actual damages sustained, treble damages for willful or flagrant violations, reasonable attorneys' fees, costs, and injunctive relief.

**SEVENTEENTH CLAIM FOR RELIEF  
VIOLATION OF THE NEW MEXICO ANTITRUST ACT,  
N.M. STAT. ANN. §§ 57-1-1, *et seq.***

403. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

404. The New Mexico Antitrust Act aims to prohibit restraints of trade and monopolistic practices. N.M. Stat. Ann. § 57-1-15.

405. Members of the class purchased abiraterone acetate within the State of New Mexico during the class period. But for the defendants' conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial.

406. Under New Mexico law, indirect purchasers have standing to maintain an action based on the facts alleged in this Complaint. N.M. Stat. Ann. § 57-1-3.

407. The defendants contracted, agreed, combined or conspired, and monopolized or attempted to monopolize trade for abiraterone acetate within the intrastate commerce of New Mexico, in violation of N.M. Stat. Ann. §§ 57-1-1 and 57-1-2, *et seq.*

408. The plaintiffs and members of the class were injured with respect to purchases of Zytiga and its AB rated generic equivalents in New Mexico and are entitled to all forms of relief, including actual damages, treble damages, reasonable attorneys' fees, costs, and injunctive relief.

**EIGHTEENTH CLAIM FOR RELIEF  
VIOLATION OF THE NEW YORK GENERAL BUSINESS LAW,  
GEN. BUS. LAW §340, *et seq.***

409. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

410. Section 340 of Article 22 of the New York General Business Law general prohibits monopolies and contracts or agreements in restraint of trade, with the policy of encouraging competition or the free exercise of any activity in the conduct of any business, trade or commerce in New York. N.Y. Gen. Bus. Law § 340(1).

411. Members of the class purchased abiraterone acetate within the State of New York during the class period. But for the defendants' conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial.

412. Under New York law, indirect purchasers have standing to maintain an action based on the facts alleged in this Complaint. N.Y. Gen. Bus. Law § 340(6).

413. The defendants established or maintained a monopoly within the intrastate commerce of New York for the trade or commerce of abiraterone acetate and restrained competition in the free exercise of the conduct of the business of abiraterone acetate within the intrastate commerce of New York, in violation of N.Y. Gen. Bus. Law § 340, *et seq.*

414. The plaintiffs and members of the class were injured with respect to purchases of Zytiga and its AB rated generic equivalents in New York and are entitled to all forms of relief, including actual damages, treble damages, costs not exceeding \$10,000, and reasonable attorneys' fees and all relief available under N.Y. Gen. Bus. Law § 349, *et seq.*

**NINETEENTH CLAIM FOR RELIEF**  
**VIOLATION OF THE NORTH CAROLINA GENERAL STATUTES,**  
**N.C. GEN. STAT. § 75-1, *et seq.***

415. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

416. The defendants entered into a contract or combination in the form of trust or otherwise, or conspiracy in restraint of trade or commerce in the abiraterone acetate market, a substantial part of which occurred within North Carolina.

417. The defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the abiraterone acetate market, for the purpose of affecting competition or controlling, fixing, or maintaining prices, a substantial part of which occurred within North Carolina.

418. The defendants' unlawful conduct substantially affected North Carolina's trade and commerce.

419. As a direct and proximate cause of the defendants' unlawful conduct, the plaintiffs and members of the class have been injured in their business or property and are threatened with further injury.

420. By reason of the foregoing, the plaintiffs and members of the class are entitled to seek all forms of relief available, including treble damages, under N.C. Gen. Stat. § 75-1, *et seq.*

**TWENTIETH CLAIM FOR RELIEF**  
**VIOLATION OF THE NORTH DAKOTA UNIFORM STATE ANTITRUST ACT,**  
**N.D. CENT. CODE § 51-08.1, *et seq.***

421. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

422. The North Dakota Uniform State Antitrust Act generally prohibits restraints on or monopolization of trade. N.D. Cent. Code § 51-08.1, *et seq.*

423. Members of the class purchased abiraterone acetate within the State of North Dakota during the class period. But for the defendants' conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial.

424. Under the North Dakota Uniform State Antitrust Act, indirect purchasers have standing to maintain an action based on the facts alleged in this Complaint. N.D. Cent. Code § 51-08.1-08.

425. The defendants contracted, combined or conspired in restraint of, or to monopolize trade or commerce in the market for abiraterone acetate, and established, maintained, or used a monopoly, or attempted to do so, for the purposes of excluding competition or controlling, fixing or maintaining prices for abiraterone acetate, in violation of N.D. Cent. Code §§ 51-08.1-02, 03.

426. The plaintiffs and members of the class were injured with respect to purchases in North Dakota and are entitled to all forms of relief, including actual damages, treble damages for flagrant violations, costs, reasonable attorneys' fees, and injunctive or other equitable relief.

**TWENTY-FIRST CLAIM FOR RELIEF  
VIOLATION OF THE OREGON ANTITRUST LAW,  
OR. REV. STAT. § 646.705, *et seq.***

427. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

428. Chapter 646 of the Oregon Revised Statutes generally governs business and trade practices within Oregon. Sections 705 through 899 thereof govern antitrust violations, with the policy to "encourage free and open competition in the interest of the general welfare and economy of the state." OR. REV. STAT. § 646.715.

429. Members of the class purchased abiraterone acetate within the State of Oregon during the class period. But for the defendants' conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial.

430. Under Oregon law, indirect purchasers have standing under the antitrust provisions of the Oregon Revised Statutes to maintain an action based on the facts alleged in this Complaint. OR. REV. STAT. § 646.780(1)(a).

431. The defendants contracted, combined, or conspired in restraint of trade or commerce of abiraterone acetate, and monopolized or attempted to monopolize the trade or commerce of abiraterone acetate, in violation of OR. REV. STAT. § 646.705, *et seq.*

432. The plaintiffs and members of the class were injured with respect to purchases of Zytiga and its AB rated generic equivalents within the intrastate commerce of Oregon, or alternatively to interstate commerce involving actual or threatened injury to persons located in Oregon, and are entitled to all forms of relief, including actual damages, treble damages, reasonable attorneys' fees, expert witness fees and investigative costs, and injunctive relief.

**TWENTY-SECOND CLAIM FOR RELIEF  
VIOLATION OF THE PUERTO RICAN ANTI-MONOPOLY ACT,  
P.R. LAWS TIT. 10, § 260, *et seq.***

433. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

434. The provisions of the Puerto Rican Anti-Monopoly Act of 1964 (the AMA) parallel Sections 1 and 2 of the Sherman Act, and other federal statutes. And those provisions are supplemented by The Regulation on Fair Competition Number VII, which proscribes certain conduct including the type engaged in by the defendants more fully described above.

435. Under the AMA, it is unlawful to monopolize, or attempt to monopolize any part of the trade or commerce in the Commonwealth of Puerto Rico. P.R. LAWS tit. 10, § 260.

436. Members of the class purchased abiraterone acetate within Puerto Rico during the class period. But for the defendants' conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial.

437. By reason of the foregoing, the plaintiffs and members of the class are entitled to seek all forms of relief available, including treble damages, attorneys' fees, and costs of suit. Puerto Rico Laws tit. 10, § 268.

**TWENTY-THIRD CLAIM FOR RELIEF  
VIOLATION OF THE RHODE ISLAND ANTITRUST ACT,  
R.I. GEN LAWS § 6-36-1, *et seq.***

438. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

439. The Rhode Island Antitrust Act aims to promote the unhampered growth of commerce and industry throughout Rhode Island by prohibiting unreasonable restraints of trade and monopolistic practices that hamper, prevent or decrease competition. R.I. Gen. Laws § 6-36-2(a)(2).

440. Under the Rhode Island Antitrust Act, as of January 1, 2008, indirect purchasers have standing to maintain an action based on the facts alleged in this Complaint. R.I. Gen. Laws § 6-36-11(a).

441. Members of the class purchased abiraterone acetate within the State of Rhode Island during the class period. But for the defendants' conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial.

442. The defendants contracted, combined and conspired in restraint of trade of abiraterone acetate within the intrastate commerce of Rhode Island, and established, maintained or used, or attempted to establish, maintain or use, a monopoly in the trade of abiraterone acetate

for the purpose of excluding competition or controlling, fixing or maintaining prices within the intrastate commerce of Rhode Island, in violation of R.I. Gen. Laws § 6-36-1, *et seq.*

443. The plaintiffs and members of the class were injured with respect to purchases of Zytiga and its AB rated generic equivalents in Rhode Island and are entitled to all forms of relief, including actual damages, treble damages, reasonable costs, reasonable attorneys' fees, and injunctive relief.

**TWENTY-FOURTH CLAIM FOR RELIEF  
VIOLATION OF THE SOUTH DAKOTA ANTITRUST STATUTE,  
S.D. CODIFIED LAWS § 37-1-3.1, *et seq.***

444. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

445. Chapter 37-1 of the South Dakota Codified Laws prohibits restraint of trade, monopolies and discriminatory trade practices. S.D. Codified Laws §§ 37-1- 3.1, 3.2.

446. Members of the class purchased abiraterone acetate within the State of South Dakota during the class period. But for the defendants' conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial.

447. Under South Dakota law, indirect purchasers have standing under the antitrust provisions of the South Dakota Codified Laws to maintain an action based on the facts alleged in this Complaint. S.D. Codified Laws § 37-1-33.

448. The defendants contracted, combined or conspired in restraint of trade or commerce of abiraterone acetate within the intrastate commerce of South Dakota, and monopolized or attempted to monopolize trade or commerce of abiraterone acetate within the intrastate commerce of South Dakota, in violation of S.D. Codified Laws § 37-1, *et seq.*

449. The plaintiffs and members of the class were injured with respect to purchases of Zytiga and its AB rated generic equivalents in South Dakota and are entitled to all forms of

relief, including actual damages, treble damages, taxable costs, reasonable attorneys' fees, and injunctive or other equitable relief.

**TWENTY-FIFTH CLAIM FOR RELIEF  
VIOLATION OF THE TENNESSEE TRADE PRACTICES ACT,  
TENN. CODE, § 47-25-101, *et seq.***

450. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

451. The Tennessee Trade Practices Act generally governs commerce and trade in Tennessee, and it prohibits, *inter alia*, all arrangements, contracts, agreements, or combinations between persons or corporations made with a view to lessen, or which tend to lessen, full and free competition in goods in Tennessee. All such arrangements, contracts, agreements, or combinations between persons or corporations designed, or which tend, to increase the prices of any such goods, are against public policy, unlawful, and void. Tenn. Code, § 47-25-101.

452. The defendants competed unfairly and colluded by meeting to fix prices, divide markets, and otherwise restrain trade as set forth herein, in violation of Tenn. Code, § 47-25-101, *et seq.*

453. The defendants' conduct violated the Tennessee Trade Practice Act because it was an arrangement, contract, agreement, or combination to lessen full and free competition in goods in Tennessee, and because it tended to increase the prices of goods in Tennessee. Specifically, the defendants' combination or conspiracy had the following effects: (1) price competition for abiraterone acetate was restrained, suppressed, and eliminated throughout Tennessee; (2) prices for abiraterone acetate were raised, fixed, maintained and stabilized at artificially high levels throughout Tennessee; (3) Plaintiff and the Tennessee Class were deprived of free and open competition; and (4) the plaintiffs and the Tennessee Class paid supra-competitive, artificially inflated prices for abiraterone acetate.

454. During the class period, the defendants' illegal conduct had a substantial effect on Tennessee commerce as abiraterone acetate was sold in Tennessee.

455. Members of the class purchased abiraterone acetate within the State of Tennessee during the class period. But for the defendants' conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial. As a direct and proximate result of the defendants' unlawful conduct, the plaintiffs and class have been injured in their business and property and are threatened with further injury.

456. Under Tennessee law, indirect purchasers (such as the plaintiffs and class) have standing under the Tennessee Trade Practice Acts to maintain an action based on the facts alleged in this complaint.

457. The plaintiffs and members of the class were injured with respect to purchases of Zytiga and its AB rated generic equivalents in Tennessee and are entitled to all forms of relief available under the law, including return of the unlawful overcharges that they paid on their purchases, damages, equitable relief, and reasonable attorneys' fees.

**TWENTY-SIXTH CLAIM FOR RELIEF  
VIOLATION OF THE UTAH ANTITRUST ACT,  
UTAH CODE ANN. §§ 76-10-3101, *et seq.***

458. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

459. The Utah Antitrust Act aims to "encourage free and open competition in the interest of the general welfare and economy of this state by prohibiting monopolistic and unfair trade practices, combinations and conspiracies in restraint of trade or commerce . . . ." Utah Code Ann. § 76-10-3102.

460. Members of the class purchased abiraterone acetate within the State of Utah during the class period. But for the defendants' conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial.

461. Under the Utah Antitrust Act, indirect purchasers who are either Utah residents or Utah citizens have standing to maintain an action based on the facts alleged in this Complaint. Utah Code Ann. § 76-10-3109(1)(a).

462. The defendants contracted, combined or conspired in restraint of trade or commerce of abiraterone acetate, and monopolized or attempted to monopolize trade or commerce of abiraterone acetate, in violation of Utah Code Ann. § 76-10-3101, *et seq.*

463. The plaintiffs and members of the class who are either Utah residents or Utah citizens were injured with respect to purchases of Zytiga and its AB rated generic equivalents in Utah and are entitled to all forms of relief, including actual damages, treble damages, costs of suit, reasonable attorneys' fees, and injunctive relief.

**TWENTY-SEVENTH CLAIM FOR RELIEF  
VIOLATION OF THE WEST VIRGINIA ANTITRUST ACT,  
W. VA. CODE §47-18-1, *et seq.***

464. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

465. The violations of federal antitrust law set forth above also constitute violations of section 47-18-1 of the West Virginia Code.

466. During the class period, defendants engaged in a continuing contract, combination or conspiracy in unreasonable restraint of trade and commerce and other anticompetitive conduct alleged above in violation of W. Va. Code §§ 47-18-1 and 47-18-20, *et seq.*

467. The defendants' anticompetitive acts described above were knowing, willful and constitute violations or flagrant violations of the West Virginia Antitrust Act.

468. As a direct and proximate result of the defendants' unlawful conduct, the plaintiffs and members of the class have been injured in their business and property in that they paid more for abiraterone acetate than they otherwise would have paid in the absence of the defendants' unlawful conduct. As a result of the defendants' violation of section 47-18-3 of the West Virginia Antitrust Act, the plaintiffs and members of the class seek treble damages and their cost of suit, including reasonable attorneys' fees, pursuant to section 47-18-9 of the West Virginia Code.

**TWENTY-EIGHTH CLAIM FOR RELIEF  
VIOLATION OF THE WISCONSIN ANTITRUST ACT,  
WIS. STAT. ANN. § 133.01(1), *et seq.***

469. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

470. Chapter 133 of the Wisconsin Statutes governs trust and monopolies, with the intent "to safeguard the public against the creation or perpetuation of monopolies and to foster and encourage competition by prohibiting unfair and discriminatory business practices which destroy or hamper competition." Wis. Stat. § 133.01.

471. Members of the class purchased abiraterone acetate within the State of Wisconsin during the class period. But for the defendants' conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial.

472. Under Wisconsin law, indirect purchasers have standing under the antitrust provisions of the Wisconsin Statutes to maintain an action based on the facts alleged in this Complaint. Wis. Stat. § 133.18(a).

473. The defendants contracted, combined or conspired in restraint of trade or commerce of abiraterone acetate, and monopolized or attempted to monopolize the trade or

commerce of abiraterone acetate, with the intention of injuring or destroying competition therein, in violation of Wis. Stat. § 133.01, *et seq.*

474. The plaintiffs and members of the class were injured with respect to purchases of Zytiga and its AB rated generic equivalents in Wisconsin in that the actions alleged herein substantially affected the people of Wisconsin, with at least thousands of consumers in Wisconsin paying substantially higher prices for the defendants' abiraterone acetate in Wisconsin.

475. Accordingly, the plaintiffs and members of the class are entitled to all forms of relief, including actual damages, treble damages, costs and reasonable attorneys' fees, and injunctive relief.

476. The defendants' anticompetitive activities have directly, foreseeably and proximately caused injury to the plaintiffs and members of the classes in the United States. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced abiraterone acetate from defendants, (2) paying higher prices for abiraterone acetate than they would have in the absence of defendants' conduct, and (3) being denied the opportunity to purchase generic abiraterone acetate at a price substantially lower than what they were forced to pay for abiraterone acetate. These injuries are of the type of the laws of the above States were designed to prevent, and flow from that which makes the defendants' conduct unlawful.

477. The defendants are jointly and severally liable for all damages suffered by the plaintiffs and members of the classes.

#### **VIOLATIONS OF STATE CONSUMER PROTECTION LAWS**

478. The plaintiffs incorporate by reference the allegations in the preceding paragraphs.

479. The defendants' above-described scheme and conduct constitutes unfair competition, unconscionable conduct, and fraudulent and deceptive acts and practices in violation of the state consumer protection statutes set forth below. As a direct and proximate result of the defendants' anticompetitive, fraudulent, deceptive, unfair, and/or unconscionable acts or practices, the plaintiffs and the class were denied the opportunity to purchase lower-priced generic versions of abiraterone acetate, and in fact paid higher prices for branded abiraterone acetate than they should have.

480. By reason of the conduct alleged herein, including the violation of federal antitrust laws, deception before the PTO, and the filing and maintaining of baseless litigation, the defendants have committed unfair, materially deceptive, and fraudulent acts and omissions in violation of the federal and state laws set forth herein.

481. The gravity of harm from the defendants' wrongful conduct significantly outweighs any conceivable utility from that conduct. The plaintiffs and class members could not reasonably have avoided injury from the defendants' wrongful conduct.

482. The plaintiffs and members of the class purchased the goods at issue, namely abiraterone acetate, primarily for personal, family, or household purposes, and not for resale.

483. There was and is a gross disparity between the price that plaintiff and the class members paid for abiraterone acetate and the value they received.

484. The following claims for relief twenty-nine through fifty-three are pleaded under the consumer protection or similar laws of each State or jurisdiction identified below, on behalf of the class.

**TWENTY-NINTH CLAIM FOR RELIEF**  
**VIOLATION OF ARIZONA CONSUMER FRAUD ACT**  
**ARIZ. REV. STAT. § 44-1521, *et seq.***

485. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

486. The Arizona Consumer Fraud Act prohibits the “act, use or employment by any person of any deception, deceptive . . . act or practice, fraud, false pretense, false promise, misrepresentation, or concealment, suppression or omission of any material fact with intent that others rely on such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise.” Ariz. Rev. Stat. § 44-1522(A).

487. By reason of the conduct alleged herein, including the violation of federal antitrust laws, deception before the PTO, and the filing and maintaining of baseless litigation, the defendants have violated the Arizona Consumer Fraud Act, Section 44-1521, *et seq.*

488. Members of the class purchased abiraterone acetate within the State of Arizona during the class period. But for the defendants’ conduct set forth herein, the price paid would have been lower, in an amount to be determined at trial.

489. The defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the abiraterone acetate market, a substantial part of which occurred within Arizona, for the purpose of excluding competition or controlling, fixing, or maintaining prices in the abiraterone acetate market.

490. The defendants’ conduct was an unfair method of competition, and an unfair or deceptive act or practice within the conduct of commerce within the State of Arizona.

491. The defendants’ unlawful conduct substantially affected Arizona’s trade and commerce.

492. As a direct and proximate cause of the defendants' unlawful conduct, the plaintiffs and members of the class have been injured in their business or property and are threatened with further injury.

493. By reason of the foregoing, the plaintiffs and the class are entitled to seek all forms of relief, including up to treble damages and reasonable attorneys' fees and costs.

**THIRTIETH CLAIM FOR RELIEF  
VIOLATION OF CALIFORNIA'S UNFAIR COMPETITION LAW  
CAL. BUS. & PROF. CODE § 17200, *et seq.* (THE "UCL")**

494. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

495. The violations of federal antitrust law set forth above also constitute violations of section 17200, *et seq.* of California Business and Professions Code.

496. California Business and Professions Code § 17200 prohibits any "unlawful, unfair, or fraudulent act or practices."

497. The defendants have engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the UCL by engaging in the acts and practices specified above.

498. This claim is instituted pursuant to sections 17203 and 17204 of California Business and Professions Code, to obtain restitution from these defendants for acts, as alleged herein, that violated the UCL.

499. The defendants' conduct as alleged herein violated the UCL. The acts, omissions, misrepresentations, practices and non-disclosures of defendants, as alleged herein, including their pursuit of *inter alia*, filing and maintaining litigation against multiple would-be generic competitors despite knowing that the '438 patent was invalid and could not be enforced, constituted a common, continuous, and continuing course of conduct of unfair competition by

means of unfair, unlawful, and/or fraudulent business acts or practices within the meaning of the UCL, including, but not limited to, the violations of section 16720, *et seq.*, of California Business and Professions Code, set forth above.

500. The defendants' acts, omissions, misrepresentations, practices, and non-disclosures, as described above, whether or not in violation of section 16720, *et seq.*, of California Business and Professions Code, and whether or not concerted or independent acts, are otherwise unfair, unconscionable, unlawful or fraudulent.

501. The plaintiffs and members of the class are entitled to full restitution and/or disgorgement of all revenues, earnings, profits, compensation, and benefits that may have been obtained by defendants as a result of such business acts or practices.

502. The unlawful and unfair business practices of the defendants, and each of them, as described above, have caused and continue to cause members of the class to pay supra-competitive and artificially-inflated prices for abiraterone acetate sold in the State of California. The plaintiffs and members of the class suffered injury in fact and lost money or property as a result of such unfair competition.

503. As alleged in this complaint, the defendants have been unjustly enriched as a result of their wrongful conduct and by the defendants' unfair competition. The plaintiffs and members of the class are accordingly entitled to equitable relief including restitution and/or disgorgement of all revenues, earnings, profits, compensation, and benefits that may have been obtained by defendants as a result of such business practices, pursuant to California Business and Professions Code sections 17203 and 17204.

**THIRTY-FIRST CLAIM FOR RELIEF  
VIOLATION OF THE DISTRICT OF COLUMBIA CONSUMER PROTECTION  
PROCEDURES ACT, D.C. CODE § 28-3901, *et seq.***

504. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

505. Members of the class purchased abiraterone acetate for personal, family, or household purposes.

506. By reason of the conduct alleged herein, including their pursuit of *inter alia*, filing and maintaining litigation against multiple would-be generic competitors despite knowing that the '438 patent was invalid and could not be enforced, the defendants have violated D.C. Code § 28-3901, *et seq.*

507. The defendants are “merchants” within the meaning of D.C. Code § 28-3901(a)(3).

508. The defendants entered into a contract, combination, or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in the abiraterone acetate market, a substantial part of which occurred within the District of Columbia.

509. The defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the abiraterone acetate market, a substantial part of which occurred within the District of Columbia, for the purpose of excluding competition or controlling, fixing, or maintaining prices in the abiraterone acetate market.

510. The defendants’ conduct was an unfair method of competition, and an unfair or deceptive act or practice within the conduct of commerce within the District of Columbia.

511. The defendants’ unlawful conduct substantially affected the District of Columbia’s trade and commerce.

512. As a direct and proximate cause of defendants' unlawful conduct, the plaintiffs and members of the class have been injured in their business or property and are threatened with further injury.

513. By reason of the foregoing, the plaintiffs and members of the class are entitled to seek all forms of relief, including treble damages or \$1500 per violation (whichever is greater) plus punitive damages, reasonable attorney's fees and costs under D.C. Code § 28-3901, *et seq.*

**THIRTY-SECOND CLAIM FOR RELIEF  
VIOLATION OF THE FLORIDA DECEPTIVE AND  
UNFAIR TRADE PRACTICES ACT,  
FLA. STAT. § 501.201(2), *et seq.***

514. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

515. The Florida Deceptive & Unfair Trade Practices Act, Florida Stat. §§ 501.201, *et seq.* (the "FDUTPA"), generally prohibits "unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce," including practices in restraint of trade. Florida Stat. § 501.204(1).

516. The primary policy of the FDUTPA is "[t]o protect the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce." Florida Stat. § 501.202(2).

517. A claim for damages under the FDUTPA has three elements: (1) a prohibited practice; (2) causation; and (3) actual damages.

518. Under Florida law, indirect purchasers have standing to maintain an action under the FDUTPA based on the facts alleged in this complaint. Fla. Stat. § 501.211(a) ("anyone aggrieved by a violation of this [statute] may bring an action . . .").

519. Members of the class purchased abiraterone acetate within the State of Florida during the class period. But for the defendants' conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial.

520. The defendants entered into a contract, combination or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in the abiraterone acetate market, a substantial part of which occurred within Florida.

521. The defendants established, maintained or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the market for abiraterone acetate, for the purpose of excluding competition or controlling, fixing or maintaining prices in Florida at a level higher than the competitive market level, beginning at least as early as 2015 and continuing through the date of this filing.

522. Accordingly, the defendants' conduct was an unfair method of competition, and an unfair or deceptive act or practice within the conduct of commerce within the State of Florida.

523. The defendants' unlawful conduct substantially affected Florida's trade and commerce.

524. As a direct and proximate cause of the defendants' unlawful conduct, the plaintiffs and members of the class have been injured in their business or property by virtue of overcharges for abiraterone acetate and are threatened with further injury.

525. By reason of the foregoing, the plaintiffs and members of the class are entitled to seek all forms of relief, including injunctive relief pursuant to Florida Stat. § 501.208 and declaratory judgment, actual damages, reasonable attorneys' fees and costs pursuant to Florida Stat. § 501.211.

**THIRTY-THIRD CLAIM FOR RELIEF  
VIOLATION OF THE HAWAII REVISED STATUTES  
ANNOTATED §§ 480-1, *et seq.***

526. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

527. The defendants have engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Hawaii Revised Statutes Annotated §§ 480-1, *et seq.*

528. The defendants' unlawful conduct had the following effects: (1) abiraterone acetate price competition was restrained, suppressed, and eliminated throughout Hawaii; (2) abiraterone acetate prices were, fixed, maintained, and stabilized at artificially high levels throughout Hawaii; (3) the plaintiffs and members of the class were deprived of free and open competition; and (4) the plaintiffs and members of the class paid supra-competitive, artificially inflated prices for abiraterone acetate.

529. During the class period, the defendants' illegal conduct substantially affected Hawaii commerce and consumers.

530. As a direct and proximate result of the defendants' unlawful conduct, the plaintiffs and members of the class have been injured and are threatened with further injury.

**THIRTY-FOURTH CLAIM FOR RELIEF  
VIOLATION OF THE IDAHO CONSUMER PROTECTION ACT,  
IDAHO CODE §§ 48-601, *et seq.***

531. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

532. The Idaho Consumer Protection Act, Idaho Code §§ 48-601, *et seq.* (the "Idaho CPA"), is a remedial statute that generally protects both consumers and businesses from "unfair methods of competition and unfair or deceptive acts and practices in the conduct of trade or

commerce” and is designed to provide “efficient and economical procedures to secure such protection.”

533. The Idaho CPA further provides that “any unconscionable method, act or practice in the conduct of any trade or commerce” expressly fall within the scope of its protection. Idaho Code §§ 48-603(18); 48-603C.

534. The Idaho CPA also contains a harmonization provision with the FTC Act. Idaho Code § 48-604(1).

535. Under Idaho law, indirect purchasers have standing to maintain an action under the Idaho CPA based on the facts alleged in this complaint. *See, e.g.*, Idaho Code § 48-608 (“Any person who purchases or leases goods or services and thereby suffers any ascertainable loss of money or property...as a result of the use or employment by another person of a method, act or practice declared unlawful by this chapter, may...bring an action to recover actual damages or one thousand dollars (\$1,000), whichever is the greater...”).

536. Members of the class purchased abiraterone acetate within the State of Idaho during the class period. But for the defendants’ conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial.

537. The defendants entered into a contract, combination or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in the abiraterone acetate market, a substantial part of which occurred within Idaho.

538. The defendants established, maintained or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the market for abiraterone acetate, for the purpose of excluding competition or controlling, fixing or maintaining prices in Idaho at a level higher

than the competitive market level, beginning at least as early as 2015 and continuing through the date of this filing.

539. Accordingly, the defendants' conduct, including their restricting consumer access to generic versions of Zytiga, was an unfair method of competition, and an unfair or deceptive act or practice within the conduct of commerce within the State of Idaho.

540. The defendants' unlawful conduct substantially affected Idaho's trade and commerce.

541. As a direct and proximate cause of the defendants' unlawful conduct, the plaintiffs and members of the class have been injured in their business or property by virtue of overcharges for abiraterone acetate and are threatened with further injury.

542. By reason of the foregoing, the plaintiffs and members of the class are entitled to seek all forms of relief, including injunctive relief, actual or statutory damages, punitive damages, and any other relief deemed necessary or proper by the court. Idaho Code § 48-608.

**THIRTY-FIFTH CLAIM FOR RELIEF**  
**VIOLATION OF THE ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS**  
**PRACTICES ACT,**  
**815 ILL. COMP. STAT. ANN. 505/10A, *et seq.***

543. The plaintiffs incorporates each and every allegation set forth in the preceding paragraphs of this complaint.

544. By reason of the conduct alleged herein, the defendants have violated 740 Ill. Comp. Stat. Ann. 10/3(1), *et seq.*

545. The defendants entered into a contract, combination, or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in the abiraterone acetate market, a substantial part of which occurred within Illinois.

546. The defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the relevant market, a substantial part of which occurred within Illinois, for the purpose of excluding competition or controlling, fixing, or maintaining prices in the abiraterone acetate market.

547. The defendants' conduct was unfair, unconscionable, or deceptive within the conduct of commerce within the State of Illinois.

548. The defendants' conduct misled consumers, withheld material facts, and resulted in material misrepresentations to the plaintiffs and members of the class.

549. The defendants' unlawful conduct substantially affected Illinois's trade and commerce.

550. As a direct and proximate cause of the defendants' unlawful conduct, the plaintiffs and members of the class were actually deceived and have been injured in their business or property and are threatened with further injury.

551. By reason of the foregoing, the plaintiffs and members of the class are entitled to seek all forms of relief, including actual damages or any other relief the Court deems proper under 815 Ill. Comp. Stat. Ann. 505/10a, *et seq.*

**THIRTY-SIXTH CLAIM FOR RELIEF  
VIOLATION OF THE MICHIGAN CONSUMER PROTECTION ACT,  
MICH. COMP. LAWS ANN. § 445.901, *et seq.***

552. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

553. By reason of the conduct alleged herein, the defendants have violated Mich. Comp. Laws Ann. § 445.901, *et seq.*

554. The defendants have entered into a contract, combination, or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in the abiraterone acetate market, a substantial part of which occurred within Michigan.

555. The defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the abiraterone acetate market, for the purpose of excluding or limiting competition or controlling or maintaining prices, a substantial part of which occurred within Michigan.

556. The defendants' conduct was conducted with the intent to deceive Michigan consumers regarding the nature of the defendants' actions within the stream of Michigan commerce.

557. The defendants' conduct was unfair, unconscionable, or deceptive within the conduct of commerce within the State of Michigan.

558. The defendants' conduct misled consumers, withheld material facts, and took advantage of the plaintiffs' and members of the class' inability to protect themselves.

559. The defendants' unlawful conduct substantially affected Michigan's trade and commerce.

560. As a direct and proximate cause of the defendants' unlawful conduct, the plaintiffs and members of the class have been injured in their business or property and are threatened with further injury.

561. By reason of the foregoing, the plaintiffs and the class are entitled to seek all forms of relief available under Mich. Comp. Laws Ann. § 445.911.

**THIRTY-SEVENTH CLAIM FOR RELIEF  
VIOLATION OF THE MINNESOTA CONSUMER FRAUD ACT,  
MINN. STAT. § 325F.68, *et seq.***

562. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

563. By reason of the conduct alleged herein, the defendants have violated Minn. Stat. § 325F.68, *et seq.*

564. The defendants engaged in a deceptive trade practice with the intent to injure competitors and consumers through supra-competitive profits.

565. The defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the abiraterone acetate market, a substantial part of which occurred within Minnesota, for the purpose of controlling, fixing, or maintaining prices in the abiraterone acetate market.

566. The defendants' conduct was unfair, unconscionable, or deceptive within the conduct of commerce within the State of Minnesota.

567. The defendants' conduct, specifically in their pursuit of *inter alia*, filing and maintaining litigation against multiple would-be generic competitors despite knowing that the '438 patent was invalid and could not be enforced, created a fraudulent or deceptive act or practice committed by a supplier in connection with a consumer transaction.

568. The defendants' unlawful conduct substantially affected Minnesota's trade and commerce.

569. The defendants' conduct was willful.

570. As a direct and proximate cause of the defendants' unlawful conduct, the plaintiffs and members of the class have been injured in their business or property and are threatened with further injury.

571. By reason of the foregoing, the plaintiffs and members of the class are entitled to seek all forms of relief, including damages, reasonable attorneys' fees and costs under Minn. Stat. § 325F.68, *et seq.* and applicable case law.

**THIRTY-EIGHTH CLAIM FOR RELIEF**  
**VIOLATION OF THE MONTANA UNFAIR TRADE PRACTICES AND CONSUMER**  
**PROTECTION ACT OF 1970,**  
**MONT. CODE, §§ 30-14-103, *et seq.*, AND §§ 30-14-201, *et. seq.***

572. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

573. The defendants have engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Montana Unfair Trade Practices and Consumer Protection Act of 1970, Mont. Code, §§ 30-14-103, *et seq.*, and §§ 30-14-201, *et. seq.*

574. The defendants' unlawful conduct had the following effects: (1) abiraterone acetate price competition was restrained, suppressed, and eliminated throughout Montana; (2) abiraterone acetate prices were raised, fixed, maintained, and stabilized at artificially high levels throughout Montana; (3) the plaintiffs and members of the class were deprived of free and open competition; and (4) the plaintiffs and members of the class paid supra-competitive, artificially inflated prices for abiraterone acetate.

575. During the class period, the defendants' illegal conduct substantially affected Montana commerce and consumers.

576. As a direct and proximate result of the defendants' unlawful conduct, the plaintiffs and members of the class have been injured and are threatened with further injury. The defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code, §§ 30-14-103, *et seq.*, and §§ 30-14-201, *et. seq.*, and, accordingly, the plaintiffs and members of the class seek all relief available under that statute.

**THIRTY-NINTH CLAIM FOR RELIEF**  
**VIOLATION OF THE NEBRASKA CONSUMER PROTECTION ACT,**  
**NEB. REV. STAT. § 59-1602, *et seq.***

577. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

578. By reason of the conduct alleged herein, the defendants have violated Neb. Rev. Stat. § 59-1602, *et seq.*

579. The defendants have entered into a contract, combination, or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in the abiraterone acetate market, a substantial part of which occurred within Nebraska.

580. The defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the abiraterone acetate market, for the purpose of excluding or limiting competition or controlling or maintaining prices, a substantial part of which occurred within Nebraska.

581. The defendants' conduct was conducted with the intent to deceive Nebraska consumers regarding the nature of the defendants' actions within the stream of Nebraska commerce.

582. The defendants' conduct was unfair, unconscionable, or deceptive within the conduct of commerce within the State of Nebraska.

583. The defendants' conduct misled consumers, withheld material facts, and had a direct or indirect impact upon the plaintiffs' and members of the-class' ability to protect themselves.

584. The defendants' unlawful conduct substantially affected Nebraska's trade and commerce.

585. As a direct and proximate cause of the defendants' unlawful conduct, the plaintiffs and members of the class have been injured in their business or property and are threatened with further injury.

586. By reason of the foregoing, the plaintiffs and members of the class are entitled to seek all forms of relief available under Neb. Rev. Stat. § 59- 1614.

**FORTIETH CLAIM FOR RELIEF  
VIOLATION OF THE NEVADA DECEPTIVE TRADE PRACTICES ACT,  
NEV. REV. STAT. § 598.0903, *et seq.***

587. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

588. By reason of the conduct alleged herein, the defendants have violated Nev. Rev. Stat. § 598.0903, *et seq.*

589. The defendants engaged in a deceptive trade practice with the intent to injure competitors and to substantially lessen competition.

590. The defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the abiraterone acetate market, a substantial part of which occurred within Nevada, for the purpose of excluding competition or controlling, fixing, or maintaining prices in the abiraterone acetate market.

591. The defendants' conduct was unfair, unconscionable, or deceptive within the conduct of commerce within the State of Nevada.

592. The defendants' conduct, including their wrongful pursuit of sham litigation they knew they could not win, amounted to a fraudulent act or practice committed by a supplier in connection with a consumer transaction.

593. The defendants' unlawful conduct substantially affected Nevada's trade and commerce.

594. The defendants' conduct was willful.

595. As a direct and proximate cause of the defendants' unlawful conduct, the members of the class have been injured in their business or property and are threatened with further injury.

596. By reason of the foregoing, the class is entitled to seek all forms of relief, including damages, reasonable attorneys' fees and costs, and a civil penalty of up to \$5,000 per violation under Nev. Rev. Stat. § 598.0993.

**FORTY-FIRST CLAIM FOR RELIEF  
VIOLATION OF THE NEW HAMPSHIRE CONSUMER PROTECTION ACT,  
N.H. REV. STAT. ANN. TIT. XXXI, § 358-A, *et seq.***

597. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

598. By reason of the conduct alleged herein, defendants have violated N.H. Rev. Stat. Ann. tit. XXXI, § 358-A, *et seq.*

599. The defendants have entered into a contract, combination, or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in the abiraterone acetate market, a substantial part of which occurred within New Hampshire.

600. The defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the abiraterone acetate market, for the purpose of excluding or limiting competition or controlling or maintaining prices, a substantial part of which occurred within New Hampshire.

601. The defendants' conduct was conducted with the intent to deceive New Hampshire consumers regarding the nature of the defendants' actions within the stream of New Hampshire commerce.

602. The defendants' conduct was unfair or deceptive within the conduct of commerce within the State of New Hampshire.

603. The defendants' conduct was willful and knowing.

604. The defendants' conduct misled consumers, withheld material facts, and had a direct or indirect impact upon the plaintiffs' and members of the class' ability to protect themselves.

605. The defendants' unlawful conduct substantially affected New Hampshire's trade and commerce.

606. As a direct and proximate cause of the defendants' unlawful conduct, the plaintiffs and the members of the class have been injured in their business or property and are threatened with further injury.

607. By reason of the foregoing, the plaintiffs and members of the class are entitled to seek all forms of relief available under N.H. Rev. Stat. Ann. tit. XXXI, §§ 358-A:10 and 358-A:10-a.

**FORTY-SECOND CLAIM FOR RELIEF  
VIOLATION OF THE NEW MEXICO UNFAIR PRACTICES ACT,  
N.M. STAT. ANN. §§ 57-12-1, *et seq.***

608. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

609. By reason of the conduct alleged herein, defendants have violated N.M. Stat. Ann. §§ 57-12-3, *et seq.*

610. The defendants entered into a contract, combination, or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in the abiraterone acetate market, a substantial part of which occurred within New Mexico.

611. The defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the relevant markets, a substantial part of which occurred within New Mexico, for the purpose of excluding competition or controlling, fixing, or maintaining prices in the abiraterone acetate market.

612. The defendants' conduct was unfair, unconscionable, or deceptive within the conduct of commerce within the State of New Mexico.

613. The defendants' conduct misled consumers, withheld material facts, and resulted in material misrepresentations to the plaintiffs and members of the class.

614. The defendants' unlawful conduct substantially affected New Mexico's trade and commerce.

615. The defendants' conduct constituted "unconscionable trade practices" in that such conduct, inter alia, resulted in a gross disparity between the value received by the New Mexico class members and the price paid by them for abiraterone acetate as set forth in N.M. Stat. Ann. § 57-12-2E.

616. The defendants' conduct was willful.

617. As a direct and proximate cause of the defendants' unlawful conduct, the plaintiffs and members of the class have been injured in their business or property and are threatened with further injury.

618. By reason of the foregoing, the plaintiffs and members of the class are entitled to seek all forms of relief, including actual damages or up to \$300 per violation, whichever is greater, plus reasonable attorney's fees under N.M. Stat. Ann. §§ 57-12-10, *et seq.*

**FORTY-THIRD CLAIM FOR RELIEF**  
**VIOLATION OF THE NEW YORK GENERAL BUSINESS LAW**  
**GEN. BUS. LAW §§ 349, *et seq.***

619. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

620. New York State General Business Law Section 349 (Section 349) broadly prohibits deceptive acts or practices in the state of New York toward the plaintiffs. In particular, Section 349 makes unlawful, *inter alia*, “[d]eceptive acts or practices in the conduct of any business, trade or commerce.” N.Y. Gen. Bus. Law §§ 349(a), (g).

621. The plaintiffs, the members of the class, and all the defendants are “persons” under N.Y. Gen. Bus. Law § 349(h),

622. The defendants’ actions as set forth herein occurred in the conduct of trade or commerce under Section 349.

623. As detailed above, the defendants engaged in deceptive acts in violation of New York and federal law in connection with Zytiga.

624. The defendants owed and continue to owe the plaintiffs and members of the Class a duty to refrain from the above-described unfair and deceptive practices.

625. The defendants knew or should have known that their conduct was in violation of Section 349.

626. The defendants’ unfair and deceptive acts or practices, omissions and misrepresentations were material to the plaintiffs and the members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including the plaintiffs and members of the Class.

627. As a result of the foregoing willful, knowing, and wrongful conduct of the defendants,

628. The plaintiff and members Class have been damaged in an amount to be proven at trial, and seek all just and proper remedies, including but not limited to actual damages, treble damages up to \$1,000, punitive damages to the extent available under the law, reasonable attorneys' fees and costs, an order enjoining the defendants' deceptive and unfair conduct, and all other just and appropriate relief available under Section 349 and New York law.

**FORTY-FOURTH CLAIM FOR RELIEF  
VIOLATION OF THE NORTH CAROLINA UNFAIR TRADE AND BUSINESS  
PRACTICES ACT,  
N.C. GEN. STAT. § 75-1.1, *et seq.***

629. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

630. By reason of the conduct alleged herein, the defendants have violated N.C. Gen. Stat. § 75-1.1, *et seq.*

631. The defendants entered into a contract, combination, or conspiracy in restraint of, or to monopolize, trade or commerce in the abiraterone acetate market, a substantial part of which occurred within North Carolina.

632. The defendants' conduct was unfair, unconscionable, or deceptive within the conduct of commerce within the State of North Carolina.

633. The defendants' trade practices are and have been immoral, unethical, unscrupulous, and substantially injurious to consumers.

634. The defendants' conduct misled consumers, withheld material facts, and resulted in material misrepresentations to the plaintiffs and members of the class.

635. The defendants' unlawful conduct substantially affected North Carolina's trade and commerce.

636. The defendants' conduct constitutes consumer-oriented deceptive acts or practices within the meaning of North Carolina law, which resulted in consumer injury and broad adverse impact on the public at large, and harmed the public interest of North Carolina consumers in an honest marketplace in which economic activity is conducted in a competitive manner.

637. As a direct and proximate cause of the defendants' unlawful conduct, the plaintiffs and members of the class have been injured in their business or property and are threatened with further injury.

638. By reason of the foregoing, the plaintiffs and members of the class are entitled to seek all forms of relief, including treble damages under N.C. Gen. Stat. § 7516.

**FORTY-FIFTH CLAIM FOR RELIEF  
VIOLATION OF THE NORTH DAKOTA UNFAIR TRADE PRACTICES LAW,  
N.D. CENT. CODE § 51-10, *et seq.***

639. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

640. By reason of the conduct alleged herein, the defendants have violated N.D. Cent. Code § 1-10-01, *et seq.*

641. The defendants engaged in a deceptive trade practice with the intent to injure competitors and consumers through supra-competitive profits.

642. The defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the abiraterone acetate market, a substantial part of which occurred within North Dakota, for the purpose of controlling, fixing, or maintaining prices in the abiraterone acetate market.

643. The defendants' conduct was unfair, unconscionable, or deceptive within the conduct of commerce within the State of North Dakota.

644. The defendants' conduct amounted to a fraudulent or deceptive act or practice committed by a supplier in connection with a consumer transaction.

645. The defendants' unlawful conduct substantially affected North Dakota's trade and commerce.

646. The defendants' conduct was willful.

647. As a direct and proximate cause of the defendants' unlawful conduct, the plaintiffs and members of the class have been injured in their business or property and are threatened with further injury.

648. By reason of the foregoing, the plaintiffs and members of the class are entitled to seek all forms of relief, including damages and injunctive relief under N.D. Cent. Code § 51-10-06.

**FORTY-SIXTH CLAIM FOR RELIEF  
VIOLATION OF THE OREGON UNLAWFUL TRADE PRACTICES ACT,  
OR. REV. STAT. § 646.605, *et seq.***

649. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

650. By reason of the conduct alleged herein, the defendants have violated Or. Rev. Stat. § 646.608, *et seq.*

651. The defendants have entered into a contract, combination, or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in the abiraterone acetate market, a substantial part of which occurred within Oregon.

652. The defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the abiraterone acetate market, for the purpose of excluding or limiting competition or controlling or maintaining prices, a substantial part of which occurred within Oregon.

653. The defendants' conduct was conducted with the intent to deceive Oregon consumers regarding the nature of the defendants' actions within the stream of Oregon commerce.

654. Defendants' conduct was unfair or deceptive within the conduct of commerce within the State of Oregon.

655. The defendants' conduct misled consumers, withheld material facts, and had a direct or indirect impact upon the plaintiffs' and members of the class' ability to protect themselves.

656. The defendants' unlawful conduct substantially affected Oregon's trade and commerce.

657. As a direct and proximate cause of the defendants' unlawful conduct, the plaintiffs and members of the class have been injured in their business or property and are threatened with further injury.

658. By reason of the foregoing, the plaintiffs and members of the class are entitled to seek all forms of relief available under OR. REV. STAT. § 646.638.

659. Pursuant to section 646.638 of the Oregon Unlawful Trade Practices Act, with the filing of this action, a copy of this complaint is being served upon the Attorney General of Oregon.

**FORTY-SEVENTH CLAIM FOR RELIEF  
VIOLATION OF THE RHODE ISLAND DECEPTIVE TRADE PRACTICES ACT,  
R.I. GEN. LAWS § 6-13.1-1, *et seq.***

660. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

661. By reason of the conduct alleged herein, the defendants have violated R.I. Gen Laws § 6-13.1-1, *et seq.*

662. The defendants engaged in an unfair or deceptive act or practice with the intent to injure competitors and consumers through supra-competitive profits.

663. The defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the abiraterone acetate market, a substantial part of which occurred within Rhode Island, for the purpose of controlling, fixing, or maintaining prices in the abiraterone acetate market.

664. The defendants' conduct was unfair or deceptive within the conduct of commerce within the State of Rhode Island.

665. The defendants' conduct amounted to an unfair or deceptive act or practice committed by a supplier in connection with a consumer transaction.

666. The defendants' unlawful conduct substantially affected Rhode Island's trade and commerce.

667. The defendants' conduct was willful.

668. The defendants deliberately failed to disclose material facts to the plaintiffs and members of the class concerning the defendants' unlawful activities, including *inter alia*, filing and maintaining litigation against multiple would-be generic competitors despite knowing that the '438 patent was invalid and could not be enforced.

669. The defendants' deception, including its affirmative misrepresentations and/or omissions concerning the price of abiraterone acetate, constitutes information necessary to the plaintiffs and members of the class relating to the cost of abiraterone acetate purchased.

670. The plaintiffs and members of the class purchased goods, namely abiraterone acetate, primarily for personal, family, or household purposes.

671. As a direct and proximate cause of the defendants' unlawful conduct, the plaintiffs and members of the class have been injured in their business or property and are threatened with further injury.

672. By reason of the foregoing, the plaintiffs and members of the class are entitled to seek all forms of relief, including actual damages or \$200 per violation, whichever is greater, and injunctive relief and punitive damages under R.I. Gen Laws § 6-13.1-5.2.

**FORTY-EIGHTH CLAIM FOR RELIEF  
VIOLATION OF THE SOUTH CAROLINA'S UNFAIR TRADE PRACTICES ACT,  
S.C. CODE ANN. §§ 39-5-10, *et seq.***

673. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

674. By reason of the conduct alleged herein, the defendants have violated S.C. Code Ann. §§ 39-5-10.

675. The defendants have entered into a contract, combination, or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in the abiraterone acetate market, a substantial part of which occurred within Oregon.

676. The defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the abiraterone acetate market, for the purpose of excluding or limiting competition or controlling or maintaining prices, a substantial part of which occurred within South Carolina.

677. The defendants' conduct was conducted with the intent to deceive South Carolina consumers regarding the nature of the defendants' actions within the stream of South Carolina commerce.

678. The defendants' conduct was unfair or deceptive within the conduct of commerce within the State of South Carolina.

679. The defendants' conduct misled consumers, withheld material facts, and had a direct or indirect impact upon the plaintiffs' and members of the class' ability to protect themselves.

680. The defendants' unlawful conduct substantially affected South Carolina trade and commerce.

681. The defendants' unlawful conduct substantially harmed the public interest of the State of South Carolina, as nearly all members of the public purchase and consume abiraterone acetate.

**FORTY-NINTH CLAIM FOR RELIEF  
VIOLATION OF THE SOUTH DAKOTA DECEPTIVE TRADE PRACTICES AND  
CONSUMER PROTECTION LAW,  
S.D. CODIFIED LAWS § 37-24, *et seq.***

682. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

683. By reason of the conduct alleged herein, the defendants have violated S.D. Codified Laws § 37-24-6.

684. The defendants engaged in a deceptive trade practice with the intent to injure competitors and consumers through supra-competitive profits.

685. The defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the abiraterone acetate market, a substantial part of which occurred within South Dakota, for the purpose of controlling, fixing, or maintaining prices in the abiraterone acetate market.

686. The defendants' conduct, including *inter alia*, filing and maintaining litigation against multiple would-be generic competitors despite knowing that the '438 patent was invalid

and could not be enforced, was unfair, unconscionable, or deceptive within the conduct of commerce within the State of South Dakota.

687. The defendants' conduct amounted to a fraudulent or deceptive act or practice committed by a supplier in connection with a consumer transaction.

688. The defendants' unlawful conduct substantially affected South Dakota's trade and commerce.

689. The defendants' conduct was willful.

690. As a direct and proximate cause of the defendants' unlawful conduct, the plaintiffs and members of the class have been injured in their business or property and are threatened with further injury.

691. By reason of the foregoing, the plaintiffs and members of the class are entitled to seek all forms of relief, including actual damages and injunctive relief under S.D. Codified Laws § 37-24-31.

**FIFTIETH CLAIM FOR RELIEF  
VIOLATION OF THE UTAH CONSUMER SALES PRACTICES ACT,  
UTAH CODE ANN. §§ 13-11-1, *et seq.***

692. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

693. By reason of the conduct alleged herein, the defendants have violated Utah Code Ann. §§ 13-11-1, *et seq.*

694. The defendants entered into a contract, combination, or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in the abiraterone acetate market, a substantial part of which occurred within Utah.

695. The defendants are suppliers within the meaning of Utah Code Ann. § 13-11-3.

696. The defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the abiraterone acetate markets, a substantial part of which occurred within Utah, for the purpose of excluding competition or controlling, fixing, or maintaining prices in the abiraterone acetate market.

697. The defendants' conduct was unfair, unconscionable, or deceptive within the conduct of commerce within the State of Utah.

698. The defendants' conduct and/or practices were unconscionable and were undertaken in connection with consumer transactions.

699. The defendants knew or had reason to know that their conduct was unconscionable.

700. The defendants' conduct misled consumers, withheld material facts, and resulted in material misrepresentations to the plaintiffs and members of the class.

701. The defendants' unlawful conduct substantially affected Utah's trade and commerce.

702. As a direct and proximate cause of the defendants' unlawful conduct, the plaintiffs and members of the class have been injured in their business or property and are threatened with further injury.

703. By reason of the foregoing, the plaintiffs and members of the class are entitled to seek all forms of relief, including declaratory judgment, injunctive relief, and ancillary relief, pursuant to Utah Code Ann. §§ 13-11-19(5) and 13-11-20.

**FIFTY-FIRST CLAIM FOR RELIEF  
VIOLATION OF THE UTAH UNFAIR PRACTICES ACT,  
UTAH CODE ALL. §§ 13-5-1, *et seq.***

704. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

705. By reason of the conduct alleged herein, the defendants have violated Utah Code Ann. §§ 13-5-1, *et seq.*

706. The defendants entered into a contract, combination, or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in the abiraterone acetate market, a substantial part of which occurred within Utah.

707. The defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the abiraterone acetate market, a substantial part of which occurred within Utah, for the purpose of excluding competition or controlling, fixing, or maintaining prices in the abiraterone acetate market.

708. The defendants' conduct caused or was intended to cause unfair methods of competition within the State of Utah.

709. The defendants' unlawful conduct substantially affected Utah's trade and commerce.

710. As a direct and proximate cause of the defendants' unlawful conduct, the plaintiffs and the members of the class have been injured in their business or property and are threatened with further injury.

711. By reason of the foregoing, the plaintiffs and the members of the class are entitled to seek all forms of relief, including actual damages or \$2000 per class member, whichever is greater, plus reasonable attorney's fees under Utah Code Ann. §§ 13-5-14, *et seq.*

**FIFTY-SECOND CLAIM FOR RELIEF  
VIOLATION OF THE VERMONT CONSUMER FRAUD ACT  
VT. STAT. ANN. TIT. 9, CH. 63 §2451, *et seq.***

712. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

713. Title 9 of the Vermont Statutes generally governs commerce and trade in Vermont. Chapter 63 thereof governs consumer protection and prohibits, *inter alia*, unfair methods competition, unfair and deceptive acts and practices, and antitrust violations such as restraints of trade and monopolization. VT. STAT ANN. tit. 9, § 2453(a).

714. Members of the class purchased abiraterone acetate within the State of Vermont during the class period. But for the defendants' conduct set forth herein, the price of abiraterone acetate would have been lower, in an amount to be determined at trial.

715. Under Vermont law, indirect purchasers have standing under the antitrust provisions of the Vermont Statutes to maintain an action based on the facts alleged in this complaint. Vt. Stat. Ann. tit. 9, § 2465(b).

716. The defendants competed unfairly by restraining trade as set forth herein, in violation of Vermont Statutes tit. 9, § 2453, *et seq.*

717. The plaintiffs and members of the class were injured with respect to purchases of Zytiga and its AB rated generic equivalents in Vermont and are entitled to all forms of relief, including actual damages, treble damages, and reasonable attorneys' fees.

**FIFTY-THIRD CLAIM FOR RELIEF**  
**VIOLATION OF THE VIRGINIA CONSUMER PROTECTION ACT**  
**VA. CODE ANN. § 59.1- 196, *et seq.***

718. The plaintiffs incorporate each and every allegation set forth in the preceding paragraphs of this complaint.

719. By reason of the conduct alleged herein, defendants have violated Va. Code Ann. §§ 59.1-196, *et seq.*

720. The defendants entered into a contract, combination, or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in the abiraterone acetate market, a substantial part of which occurred within Virginia.

721. The defendants established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the abiraterone acetate market, a substantial part of which occurred within Virginia, for the purpose of excluding competition or controlling, fixing, or maintaining prices in the abiraterone acetate market.

722. The defendants' conduct caused or was intended to cause unfair methods of competition within the State of Virginia.

723. The defendants' unlawful conduct substantially affected Virginia's trade and commerce.

724. As a direct and proximate cause of defendants' unlawful conduct, the plaintiffs and members of the class have been injured in their business or property and are threatened with further injury.

725. By reason of the foregoing, the plaintiffs and the members of the class are entitled to seek all forms of relief, including actual damages, treble damages, plus reasonable attorney's fees under Virginia Code Ann. § 59.1-196, *et seq.*

#### **FIFTY-FOURTH CLAIM FOR RELIEF: UNJUST ENRICHMENT**

726. The plaintiffs incorporate by reference the allegations in the preceding paragraphs.

727. To the extent required, this claim is pled in the alternative to the other claims in this complaint.

728. It would be futile for the plaintiffs, or any member of the class, to seek a remedy from any party with whom they had or have privity of contract; the defendants have paid no consideration to anyone for the improper benefits they received indirectly from the plaintiffs and members of the class.

729. As a result of their unlawful conduct described above, the defendants have and will continued to be unjustly enriched by the receipt of unlawfully inflated prices and unlawful profits of abiraterone acetate.

730. A constructive trust should be imposed upon all unlawful or inequitable sums the defendants received that are traceable to the plaintiffs and members of the class.

#### **ALABAMA**

731. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Alabama at prices that were more than they would have been but for the defendants' actions. The defendants received money from the Class as a direct result of the unlawful overcharges and have retained this money. The defendants have benefitted at the expense of the Class from revenue resulting from unlawful overcharges for Zytiga or its AB-rated generic equivalents. It is inequitable for the defendants to accept and retain the benefits received without compensating the Class.

#### **ALASKA**

732. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Alaska at prices that were more than they would have been but for the defendants' actions. The Class has conferred an economic benefit upon the defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. The defendants appreciated the benefits bestowed upon them by the Class. The defendants accepted and retained the benefits bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to the Class. Under the circumstances, it would be inequitable for the defendants to retain such benefits without compensating the Class.

### **ARIZONA**

733. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Arizona at prices that were more than they would have been but for the defendants' actions. The defendants have been enriched by revenue resulting from unlawful overcharges for Zytiga or its AB-rated generic equivalents. The Class has been impoverished by the overcharges for Zytiga or its AB-rated generic equivalents resulting from the defendants' unlawful conduct. The defendants' enrichment and the Class's impoverishment are connected. There is no justification for the defendants' receipt of the benefits causing their enrichment and the Class's impoverishment, because the Class paid supra-competitive prices that inured to the defendants' benefit, and it would be inequitable for the defendants to retain any revenue gained from their unlawful overcharges. The Class has no remedy at law.

### **ARKANSAS**

734. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Arkansas at prices that were more than they would have been but for the defendants' actions. The defendants received money from the Class as a direct result of the unlawful overcharges and have retained this money. The defendants have paid no consideration to any other person in exchange for this money. Under the circumstances, it would be inequitable for the defendants to retain such benefits without compensating the Class.

### **CALIFORNIA**

735. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in California at prices that were more than they would have been but for the defendants' actions. The defendants have received a

benefit from the Class as a direct result of the unlawful overcharges. The defendants retained the benefits bestowed upon them under inequitable and unjust circumstances at the expense of the Class.

#### **DISTRICT OF COLUMBIA**

736. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in the District of Columbia at prices that were more than they would have been but for the defendants' actions. The Class has conferred an economic benefit upon the defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. The defendants retained the benefit bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to the Class. Under the circumstances, it would be inequitable and unjust for the defendants to retain such benefits.

#### **FLORIDA**

737. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Florida at prices that were more than they would have been but for the defendants' actions. The Class has conferred an economic benefit upon the defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. The defendants appreciated the benefits bestowed upon them by the Class. Under the circumstances, it would be inequitable for the defendants to retain such benefits without compensating the Class.

#### **GEORGIA**

738. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Georgia at prices that were more than they would have been but for the defendants' actions. The Class has conferred an

economic benefit upon the defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Under the circumstances, it would be inequitable for the defendants to retain such benefits without compensating the Class.

#### **HAWAII**

739. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Hawaii at prices that were more than they would have been but for the defendants' actions. The Class has conferred an economic benefit upon the defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Under the circumstances, it would be inequitable for the defendants to retain such benefits without compensating the Class.

#### **IDAHO**

740. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Idaho at prices that were more than they would have been but for the defendants' actions. The Class has conferred an economic benefit upon the defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. The defendants appreciated the benefit conferred upon them by the Class. Under the circumstances, it would be inequitable for the defendants to retain such benefits without compensating the Class.

#### **ILLINOIS**

741. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Illinois at prices that were more than they would have been but for the defendants' actions. The Class has conferred an economic benefit upon the defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. The defendants retained the benefits

bestowed upon them under unjust circumstances arising from unlawful overcharges to the Class. It is against equity, justice, and good conscience for the defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

#### **IOWA**

742. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Iowa at prices that were more than they would have been but for the defendants' actions. The defendants have been enriched by revenue resulting from unlawful overcharges for Zytiga or its AB-rated generic equivalents, which revenue resulted from anticompetitive prices paid by d the Class, which inured to the defendants' benefit. The defendants' enrichment has occurred at the expense of the Class. Under the circumstances, it would be unjust for the defendants to retain such benefits without compensating the Class.

#### **KANSAS**

743. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Kansas at prices that were more than they would have been but for the defendants' actions. The Class has conferred an economic benefit upon the defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. The defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to the Class. Under the circumstances, it would be inequitable for the defendants to retain such benefits without compensating the Class.

#### **MAINE**

744. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Maine at prices that were

more than they would have been but for the defendants' actions. The Class has conferred an economic benefit upon the defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. The defendants were aware of or appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for the defendants to retain such benefits without compensating the Class.

#### **MARYLAND**

745. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Maryland at prices that were more than they would have been but for the defendants' actions. The Class has conferred an economic benefit upon the defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. The defendants were aware of or appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for the defendants to retain such benefits without compensating the Class.

#### **MASSACHUSETTS**

746. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Massachusetts at prices that were more than they would have been but for the defendants' actions. The Class has conferred an economic benefit upon the defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. The defendants were aware of or appreciated the benefit conferred upon them by the Class. Under the circumstances, it would be inequitable for the defendants to retain such benefits without compensating the Class.<sup>32</sup>

---

<sup>32</sup> Plaintiff intends to assert a claim under Mass. Gen Laws Ch. 93A, § 1, *et seq.*, after providing notice to the appropriate party.

### **MICHIGAN**

747. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Michigan at prices that were more than they would have been but for the defendants' actions. The defendants have received a benefit from the Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of the defendants. The defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to the Class. Under the circumstances, it would be inequitable for the defendants to retain such benefits without compensating the Class.

### **MINNESOTA**

748. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Minnesota at prices that were more than they would have been but for the defendants' actions. The Class has conferred an economic benefit upon the defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. The defendants appreciated and knowingly accepted the benefits bestowed upon them by the Class. Under the circumstances, it would be inequitable for the defendants to retain such benefits without compensating the Class.

### **MISSISSIPPI**

749. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Mississippi at prices that were more than they would have been but for the defendants' actions. The defendants received money from the Class as a direct result of the unlawful overcharges. The defendants retain the benefit of overcharges received on the sales of Zytiga or its AB-rated generic equivalents, which in equity and good conscience belong to the Class on account of the defendants' anticompetitive

conduct. Under the circumstances, it would be inequitable for the defendants to retain such benefits without compensating the Class.

#### **MISSOURI**

750. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Missouri at prices that were more than they would have been but for the defendants' actions. The Class has conferred an economic benefit upon the defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. The defendants appreciated the benefit bestowed upon them by the Class. The defendants accepted and retained the benefit bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to the Class.

#### **MONTANA**

751. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Montana at prices that were more than they would have been but for the defendants' actions. The Class has conferred an economic benefit upon the defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Under the circumstances, it would be inequitable for the defendants to retain such benefits without compensating the Class.

#### **NEBRASKA**

752. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Nebraska at prices that were more than they would have been but for the defendants' actions. The defendants received money from the Class as a direct result of the unlawful overcharges and have retained this money. The defendants have paid no consideration to any other person in exchange for this money. In justice

and fairness, the defendants should disgorge such money and remit the overcharged payments back to the Class.

#### **NEVADA**

753. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Nevada at prices that were more than they would have been but for the defendants' actions. The Class has conferred an economic benefit upon the defendants in the nature of revenue resulting from unlawful overcharges for Zytiga or its AB-rated generic equivalents. The defendants appreciated the benefits bestowed upon them by the Class, for which they have paid no consideration to any other person. Under the circumstances, it would be inequitable for the defendants to retain such benefits without compensating the Class.

#### **NEW HAMPSHIRE**

754. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in New Hampshire at prices that were more than they would have been but for the defendants' actions. The defendants have received a benefit from the Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of the defendants. Under the circumstances, it would be unconscionable for the defendants to retain such benefits.

#### **NEW MEXICO**

755. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in New Mexico at prices that were more than they would have been but for Defendants' actions. The defendants have knowingly benefitted at the expense of the Class from revenue resulting from unlawful

overcharges for Zytiga or its AB-rated generic equivalents. To allow the defendants to retain the benefits would be unjust because the benefits resulted from anticompetitive pricing that inured to the defendants' benefit and because the defendants have paid no consideration to any other person for any of the benefits they received.

#### **NEW YORK**

756. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in New York at prices that were more than they would have been but for the defendants' actions. The defendants have been enriched by revenue resulting from unlawful overcharges for Zytiga or its AB-rated generic equivalents, which revenue resulted from anticompetitive prices paid by the Class, which inured to the defendants' benefit. The defendants' enrichment has occurred at the expense of the Class. It is against equity and good conscience for the defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

#### **NORTH CAROLINA**

757. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in North Carolina at prices that were more than they would have been but for the defendants' actions. The Class has conferred an economic benefit upon the defendants in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. The Class did not interfere with the defendants' affairs in any manner that conferred these benefits upon the defendants. The benefits conferred upon the defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from arising from unlawful overcharges to the Class. The benefits conferred upon the defendants are measurable, in that the revenue the defendants have earned

due to unlawful overcharges are ascertainable by review of sales records. The defendants consciously accepted the benefits conferred upon them.

#### **NORTH DAKOTA**

758. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in North Dakota at prices that were more than they would have been but for the defendants' actions. The defendants have been enriched by revenue resulting from unlawful overcharges for Zytiga or its AB-rated generic equivalents. The Class has been impoverished by the overcharges for Zytiga or its AB-rated generic equivalents resulting from the defendants' unlawful conduct. The defendants' enrichment and the Class's impoverishment are connected. There is no justification for the defendants' receipt of the benefits causing their enrichment, because the Class paid supra-competitive prices that inured to the defendants' benefit, and it would be inequitable for the defendants to retain any revenue gained from their unlawful overcharges. The Class has no remedy at law. Under the circumstances, it would be unjust for the defendants to retain such benefits without compensating the Class.

#### **OREGON**

759. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Oregon at prices that were more than they would have been but for the defendants' actions. The Class has conferred an economic benefit upon the defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. The defendants were aware of the benefit bestowed upon them by the Class. Under the circumstances, it would be unjust for the defendants to retain such benefits without compensating the Class.

### **PENNSYLVANIA**

760. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Pennsylvania at prices that were more than they would have been but for the defendants' actions. The Class has conferred an economic benefit upon the defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. The defendants appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for the defendants to retain such benefits without compensating the Class.

### **PUERTO RICO**

761. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Puerto Rico at prices that were more than they would have been but for the defendants' actions. The defendants have been enriched by revenue resulting from unlawful overcharges for Zytiga or its AB-rated generic equivalents. The Class has been impoverished by the overcharges for Zytiga or its AB-rated generic equivalents resulting from the defendants' unlawful conduct. The defendants' enrichment and the Class's impoverishment are connected. There is no justification for the defendants' receipt of the benefits causing their enrichment and the Class's impoverishment, because the Class paid supra-competitive prices that inured to the defendants' benefit, and it would be inequitable for the defendants to retain any revenue gained from their unlawful overcharges. The Class has no remedy at law.

### **RHODE ISLAND**

762. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Rhode Island at prices that were more than they would have been but for the defendants' actions. The Class has conferred an

economic benefit upon the defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. The defendants appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for the defendants to retain such benefits without compensating the Class.

#### **SOUTH CAROLINA**

763. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in South Carolina at prices that were more than they would have been but for the defendants' actions. The benefits conferred upon the defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from arising from unlawful overcharges to the Class. The defendants realized value from the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for the defendants to retain such benefits without compensating the Class.

#### **SOUTH DAKOTA**

764. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in South Dakota at prices that were more than they would have been but for the defendants' actions. The defendants have received a benefit from the Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of defendants. The defendants were aware of the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable and unjust for the defendants to retain such benefits without reimbursing the Class.

#### **TENNESSEE**

765. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Tennessee at prices that were

more than they would have been but for the defendants' actions. The Class has conferred an economic benefit upon the defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. The defendants appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for the defendants to retain such benefits without compensating the Class. It would be futile for the Class to seek a remedy from any party with whom they have privity of contract. The defendants have paid no consideration to any other person for any of the unlawful benefits they received indirectly from the Class with respect to the defendants' sales of Zytiga or its AB-rated generic equivalents. It would be futile for The Class to exhaust all remedies against the entities with which the Class has privity of contract because the Class did not purchase Zytiga or its AB-rated generic equivalents directly from any defendant.

#### **UTAH**

766. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Utah at prices that were more than they would have been but for the defendants' actions. The Class has conferred an economic benefit upon the defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. The defendants were aware of or appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for the defendants to retain such benefits without compensating the Class.

#### **VERMONT**

767. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Vermont at prices that were more than they would have been but for the defendants' actions. The Class has conferred an economic benefit upon defendants, in the nature of revenue resulting from unlawful overcharges

to the economic detriment of the Class. The defendants accepted the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for the defendants to retain such benefits without compensating the Class.

### **VIRGINIA**

768. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Virginia at prices that were more than they would have been but for the defendants' actions. The Class has conferred an economic benefit upon the defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. The defendants were aware of the benefit bestowed upon them. The defendants should reasonably have expected to repay the Class. The benefits conferred upon the defendants were not gratuitous, in that they constituted revenue created by unlawful overcharges arising from the defendants' illegal and unfair actions to inflate the prices of Zytiga or its AB-rated generic equivalents. The defendants have paid no consideration to any other person for any of the benefits they have received from the Class.

### **WEST VIRGINIA**

769. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in West Virginia at prices that were more than they would have been but for the defendants' actions. The Class has conferred an economic benefit upon the defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. The defendants were aware of or

appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for the defendants to retain such benefits without compensating the Class.<sup>33</sup>

#### **WISCONSIN**

770. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Wisconsin at prices that were more than they would have been but for the defendants' actions. The Class has conferred an economic benefit upon the defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. The defendants appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for the defendants to retain such benefits without compensating the Class.

#### **WYOMING**

771. The defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Zytiga or its AB-rated generic equivalents in Wyoming at prices that were more than they would have been but for the defendants' actions. The Class has conferred an economic benefit upon the defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. The defendants accepted, used and enjoyed the benefits bestowed upon them by the Class. Under the circumstances, it would be inequitable for the defendants to retain such benefits without compensating the Class.

#### **COMPLIANCE WITH NOTICE REQUIREMENTS**

772. In accordance with the requirements of Arizona Revised Statute § 44-1415, 5 Maine Revised Statute § 213(3), Nevada Revised Statute § 598A.210(3), New York General Business Law § 340(5), Rhode Island General Laws § 6-36-21, Utah Code Ann. § 76-10-

---

<sup>33</sup> Plaintiff intends to assert a claim under W. Va. Code § 46A-6-101, *et seq.*, after providing notice to the appropriate party.

2109(9), and West Virginia Code §46A-6-106(a) upon filing counsel will send letters by certified mail, return receipt requested, to:

- a. Mark Brnovich, Attorney General of Arizona;
- b. Aaron Frey, Attorney General of Maine;
- c. Aaron Ford, Attorney General of Nevada;
- d. Letita James, Attorney General of New York;
- e. Peter Neronha, Attorney General of Rhode Island; and
- f. Sean Reyes, Attorney General of Utah; and
- g. Patrick Morrissey, Attorney General of West Virginia.

informing them of the existence of this Class Action Complaint, identifying the relevant state antitrust provisions, and enclosing a copy of this Class Action Complaint.

**FIFTY-FIFTH CLAIM FOR RELIEF: VIOLATION OF SHERMAN ACT, 15 U.S.C. § 2**

773. The plaintiffs incorporate by reference all previous allegations of fact.

774. This count seeks monetary relief under section 4 of the Clayton Act for conduct in violation of section 2 of the Sherman Act on behalf of the plaintiffs and all members of the class, for their purchases of Zytiga and/or generic abiraterone acetate.

775. Increasingly over the past decade, a distribution model of “specialty pharmacy” has become a dominant sector in the United States. While originally modelled to address a narrow range of non-self-administered pharmaceuticals that truly required special handling and service for patients, the use of the model has widened considerably over time, leading to a loose use of the term. Industry organizations have therefore developed definitions of the specialty model. As self-described, “[c]ommonalities seen within the definitions include the distribution of specialty pharmaceuticals and high-touch, patient-centered management that maximally benefits

the patient's medication experience. Ideally, this translates into improved care with measurable, positive clinical outcomes.”

776. Specialty pharmacies offer services beyond those typically offered by either distributors or traditional pharmacies. These include: 24-hour access to pharmacists; adherence management; benefits investigation; communication and follow-up with the physician; dispensing of specialty pharmaceuticals and shipping coordination; enrollment in patient assistance programs; financial assistance; patient education and medication adverse effect counseling; patient monitoring for safety and efficacy; payer and/or manufacturer reporting; proactive patient outreach for prescription refill and renewal, and; prior authorization assistance.

777. These services are designed not only to aid patient care, but also to foster use the manufacturer-sponsor's products. The manufacturer pays the distributor for these services; because of those services, the manufacturer can command higher prices for the product and can ensure better, more continued sales. For the same reason, the specialty pharmacy, i.e., the distributor earns greater revenue and profits the more it can foster the use of the manufacturer's products.

778. Specialty pharmacy, which once occupied only a small niche in the marketplace, has become a major segment of the pharmaceutical industry.

779. Within the general area of specialty pharmacy, there is even a narrower sub-distribution system known as *limited-distribution* specialty pharmacy. While some medications are supplied by many different specialty pharmacies throughout the nation, limited distribution drugs, on the other hand, are only available through a select few. Pharmaceutical manufacturers typically identify this smaller group of specialty pharmacies by their higher capability to achieve the joint goals of the companies.

780. Pharmaceutical manufacturers therefore at times choose to limit the distribution of a drug to only a few specialty pharmacies. Common disease states managed by limited distribution specialty pharmacies include oncology, multiple sclerosis, rheumatoid arthritis, HIV/AIDS, and hepatitis C.

781. The manufacturer of a “specialty drug” and its limited distribution, specialty pharmacy are often referred to as “partners.” As one such limited distributor touts, it “is extremely proud to have been selected as a limited distribution drug *partner* by manufacturers for many different medications over the years . . . .”

782. Janssen causes Zytiga to be distributed into the United States marketplace through a carefully selected, small group of limited distribution specialty pharmacies controlled by Janssen. As a result, abiraterone is only available through an exclusive, limited-distribution specialty pharmacy network each member of which is paid by Janssen to distribute Zytiga.

783. In addition to acting as Janssen’s agent for the distribution of Zytiga, the small group of limited-distribution specialty pharmacies perform other services on behalf of Janssen. Janssen pays for these services. For example, these specialty pharmacies ostensibly have the capability of providing clinical support and patient oversight to enable the continued use of Zytiga and other Janssen products; along with dispensing the medication to the patient, these specialty pharmacies counsel the patient on the administration, ostensible expected benefits, and potential adverse effects of the medication; outbound phone calls by both pharmacists and the network’s nurses can be scheduled for Janssen’s therapies, designed to help guide the patient through his therapeutic care plan while enhancing the patient–pharmacy relationship. Many specialty pharmacies have the ability to monitor a patient’s disease progression, medication adherence, report quality of life, and can trigger interventions specific to the identified

complication. These specialty pharmacy services have been critical to the success of Zytiga and have helped optimize use of Zytiga for thousands of patients in recent years.

784. On information and belief, the network of Janssen's limited distribution specialty pharmacies for Zytiga has not, at any one time during the class period for this case, exceeded more than 16 members. These include the specialty pharmacy operations of Accredo Health, Avella Specialty Pharmacy, CVS/Caremark, Diplomat Specialty, U.S. Bioservices, and Alliance/Walgreens.

785. Given the unique business relationship between Janssen and the members of its limited distribution specialty pharmacy network for Zytiga, the limited distribution players act as agents for Janssen for Janssen's distribution of Zytiga nationwide. And there are multiple reasons why the relationship between Janssen and its Zytiga distribution agents creates a situation where there is neither a likelihood nor ability for its distribution agents to enforce antitrust laws violated by Janssen where that violation is of the type raised by this case, i.e., depriving access to AB-rated generic equivalents.

786. First, unlike most manufacturer-distributor relationships (where the distributor makes its profit by buying low from the manufacturer and selling at a higher price to a downstream purchaser), here Janssen actually *pays the distributor agents* to distribute the product. And the more the distributor agent distributes Janssen's Zytiga, the more money it makes from payments from Janssen. As a result, Janssen and the distributor agents share the goal of keeping Zytiga in a monopoly position—each make more and more revenue the longer the product remains on the market alone—rather than seeing the entry of a generic Zytiga that would take sales away from that arrangement.

787. Second, on information and belief, Janssen functionally controls not only the price paid by the Zytiga distribution agents to purchase Zytiga, but also the prices charged by those distributors to downstream purchasers. Among other things, purchases by downstream stakeholders including the patients themselves are closely monitored and coordinated by Janssen; as a result, competition between distributor agents is minimized. And because most revenue is earned by the distributor agent on the “buy-side,” and the Zytiga distributor agents provide the same, contractually-required specialty services, they lack reason to undercut efforts by Janssen to control the resale price of Zytiga.

788. For these and other reasons, Janssen functionally controls the resale price of Zytiga. For example, while a single health plan might be paying five or six of Janssen’s distributor agents for a 30-day supply of Zytiga at multiple locations across the nation and for different patients, the amounts charged by those different specialty pharmacies for the ingredient cost of Zytiga are, to the penny, exactly the same (e.g., \$10,221.93).

789. Third—and not only do Janssen’s distributor agents make most of their revenues on the “buy-side” of the Zytiga transaction— Janssen’s distributor agents do not necessarily suffer an overcharge due to the absence of AB-rated generic competition for a limited distribution drug. In the usual distribution circumstances, all or virtually all distributors suffer an overcharge from the absence of AB-rated generics because all or virtually all of them purchase the brand and the generic versions of the drug. However, in the marketplace for Zytiga and its generic counterparts, no Janssen limited distributor is guaranteed access to directly purchase and sell the generic counterpart when, as and if it comes on the market, let alone play a role as the specialty pharmacy distributor who gets compensated by the generic seller to perform specialty

services. As a result, absent a showing that they had a right to both purchase generic Zytiga and continue specialty services, they likely suffer no overcharge.

790. Fourth, being a member of Janssen's limited distribution specialty pharmacy network for Zytiga is highly lucrative and carefully guarded. And unlike the traditional distribution system where brand manufacturers need the traditional distributors to make their products widely available, here manufacturers of limited distribution drugs may pick and choose who may become a member of their network. As a result, the distributor agents have no reason to upset a source of highly profitable work. They are not going to bite the hand that feeds them.

791. In summary, Janssen controls its distribution network through agents that it pays; these agents have no antitrust claim to bring against Janssen when the allegation is delayed generic entry; Janssen controls all aspects of the distribution arrangement, including the buy and sell price of its agents. As a result, it is the Zytiga purchasers from Janssen's distributor agents, and not distributor agents themselves, that are the direct purchasers for purposes of an antitrust case such as this that alleges delayed generic entry.

792. The plaintiffs purchased Zytiga directly from Janssen's distributor agents during the class period, including of Accredo Health, Avella Specialty Pharmacy, CVS/Caremark, Diplomat Specialty, U.S. Bioservices, and Alliance/Walgreens. As a result, the plaintiffs have standing under section 4 of the Clayton Act to seek damages for violation of federal law under section 2 of the Sherman Act.

793. Janssen violated 15 U.S.C. § 2 through its acts of pursuing sham litigation, all as previously alleged. The plaintiff and all direct purchasers have been injured in their business or property by the violation of 15 U.S.C. § 2. The direct purchasers' injury consists of having paid higher prices for Zytiga than they otherwise would have paid in the absence of that violation.

**X. DEMAND FOR JUDGMENT**

WHEREFORE, the plaintiffs, on behalf of themselves and the class of all others so similarly situated, respectfully requests judgment against the defendants as follows:

794. The Court determine that this action may be maintained as a class action under Rule 23(a), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure, appoint the plaintiff as class representative and their counsel of record as class counsel, and direct that notice of this action, as provided by Rule 23(c)(2) of the Federal Rules of Civil Procedure, be given to the class, once certified;

795. The unlawful conduct, conspiracy or combination alleged herein be adjudged and decreed in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2 and the listed state antitrust laws, unfair competition laws, state consumer protection laws, and common law;

796. The plaintiffs and the class recover damages, to the maximum extent allowed under the Sherman Act and the applicable state laws, and that a joint and several judgment in favor of the plaintiffs and members of the classes be entered in an amount to be trebled to the extent such laws permit;

797. The plaintiffs and the members of the class be awarded pre- and post- judgment interest as provided by law, and that such interest be awarded at the highest legal rate from and after the date of service of this complaint;

798. The plaintiffs and members of the class recover their costs of suit, including reasonable attorneys' fees, as provided by law; and

799. The plaintiffs and members of the class have such other and further relief as the case may require and the Court may deem just and proper.

## **XI. JURY DEMAND**

800. Pursuant to Rule 38 of the Federal Rules of Civil Procedure, the plaintiffs, on behalf of themselves and the proposed class, demand a trial by jury of all issues so triable.

Dated: April 18, 2019

/s/

William H. Monroe, Jr. (VSB No. 27441)

Marc C. Greco (VSB No. 41496)

Kip A. Harbison (VSB No. 38648)

Michael A. Glasser (VSB No. 17651)

William D. Moore, III (VSB No. 77097)

Anders T. Sleight (VSB No. 84458)

GLASSER AND GLASSER, P.L.C.

Crown Center, Suite 600

580 East Main Street

Norfolk, VA 23510

Telephone: (757) 625-6787

Facsimile: (757) 625-5959

bill@glasserlaw.com

marcg@glasserlaw.com

kip@glasserlaw.com

michael@glasserlaw.com

[wmoore@glasserlaw.com](mailto:wmoore@glasserlaw.com)

[asleight@glasserlaw.com](mailto:asleight@glasserlaw.com)

*Local Counsel for Plaintiffs Louisiana Health  
Service & Indemnity Company d/b/a Blue Cross and  
Blue Shield of Louisiana, HMO Louisiana, Inc. and  
the Proposed Class*

Thomas M. Sobol

Lauren G. Barnes

Gregory T. Arnold

Bradley J. Vettraino

HAGENS BERMAN SOBOL SHAPIRO LLP

55 Cambridge Parkway, Suite 301

Cambridge, MA 02142

Telephone: (617) 482-3700

Facsimile: (617) 482-3003

tom@hbsslaw.com

lauren@hbsslaw.com

grega@hbsslaw.com

bradleyv@hbsslaw.com

James R. Dugan II (*pro hac vice* forthcoming)  
David S. Scalia (*pro hac vice* forthcoming)  
THE DUGAN LAW FIRM, LLC  
One Canal Place, Suite 1000  
365 Canal Street  
New Orleans, LA 70130  
Telephone: (504) 648-0180  
Facsimile: (504) 648-0181  
jdugan@dugan-lawfirm.com  
dscaliam@dugan-lawfirm.com

*Counsel for Plaintiffs Louisiana Health Service &  
Indemnity Company d/b/a Blue Cross and Blue  
Shield of Louisiana, HMO Louisiana, Inc. and the  
Proposed Class*

Allison N. Pham  
Jessica Chapman  
Charles A. O'Brien  
LOUISIANA HEALTH SERVICE & INDEMNITY  
COMPANY, D/B/A BLUE CROSS AND BLUE SHIELD OF  
LOUISIANA  
5525 Reitz Avenue  
P.O. Box 98029  
Baton Rouge, LA 70809  
Telephone: (225) 295-2199  
Facsimile: (225) 297-2760

*Counsel for Plaintiffs Louisiana Health Service &  
Indemnity Company d/b/a Blue Cross and Blue  
Shield of Louisiana, HMO Louisiana, Inc.*